

PATIENT MONITOR

PM 9000+

CONTROLLED COPY

MANUAL BOOK

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### **Responsibility on the manufacturer party**

Our company is responsible for safety, reliability and performance of this equipment only in the conditions that:

- All installation, expansion, change, modification and repair of this equipment are conducted by our qualified personnel; and,
- Applied electrical appliance is in compliance with relevant National Standards; and,

- The monitor is operated under strict observance of this manual.

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#### WARNING

- This monitor is not a device for treatment purpose.

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#### NOTE:

- This equipment is not intended for family usage.
- Whether the instrument supports the functions described in this manual, please refer to the actual object.

It is important for the hospital or organization that employs this equipment to carry out a reasonable maintenance schedule. Neglect of this may result in machine breakdown or injury of human health.

Upon request, our company may provide, with compensation, necessary circuit diagrams, calibration illustration list and other information to help qualified technician to maintain and repair some parts, which our company may define as user serviceable.

## **Warranty**

### **Workmanship & Materials**

Our company guarantees new equipment other than accessories to be free from defects in workmanship and materials for a period of 24 months from date of shipment under normal use and service. Our company's obligation under this warranty is limited to repairing only.

### **Exemptions**

Our company's obligation or liability under this warranty does not include any transportation or other charges or liability for direct, indirect or consequential damages or delay resulting from the improper use or application of parts or accessories of the product or the substitution upon it not approved by us or repaired by anyone other than our company authorized personal. This warranty shall not extend to any instrument which has been subjected to abnormal use, maintenance negligence or damaged; any instrument from which our company's original serial number tag or product identification markings have been altered or removed, or any product of any other manufacturer.

### **Safety, Reliability and Performance**

Our company is not responsible for the effects on safety, reliability and performance of the Monitor if:

- The components are disassembled, stretched or re-adjusted.
- The Monitor is not used in accordance with the instructions for use, or the electrical installation of the relevant room does not comply with NFPA 70: National Electrical Code or NFPA 99: Standard for Health Care Facilities (Outside the United States, the relevant room must comply with all electrical installation regulations mandated by the local and regional bodies of government).

## **Return Policy**

### **Return Procedure**

In the event that it becomes necessary to return a unit to our company, the following procedure should be followed:

- Obtain return authorization. Contact our Service Department and tell us the product serial number. The number is marked on the outside of the shipping package. Return shipments would not be accepted if the number is not clearly visible. Please provide the model number, serial number, and a brief description of the reason for return.
- Freight policy. The customer is responsible for freight charges when equipment is shipped to our company for service (this includes customs charges).

### **Preface**

Thank you for choosing Elitech® as your medical device choice. This manual gives detailed description to the Monitor concerning its performance, operation, and other safety information. Please read the user manual carefully before use in order to operate this product correctly and guarantee the safety of patient and operator.

Keep the user manual near the product for convenient and timely accessed when needed.

Following symbols represent some important facts that you have to pay special attention to:

Safety warnings indicate the severity of potential hazards.

**Warning:** prompting potential dangerous or unsafe operations, if not avoided, it may result in death or severe personal injury or property damage.

**Caution:** prompting potential dangerous or unsafe operations, if not avoided, it

may result in slight personal injury, product failure or damage, or property damage.

**Note:** emphasizing important attentions, providing explanations or interpretations for better use.

**NOTE:**

- The user manual contains descriptions concerning all configurations, so part of the content may not suitable for the product your purchased. If you have any doubts, please contact with us.
- Refer to the device for its date of manufacture and service life.

This manual is intended for persons who are familiar with the functioning measurements and have experience in operating the monitoring equipment.

## Contents

Chapter 1 Safety.....	1
1.1 Safety information.....	1
1.2 Precautionary measures .....	4
1.3 Symbols .....	5
Chapter 2 General .....	7
2.1 Introduction .....	7
2.2 Contraindications .....	7
2.3 Main unit.....	7
2.4 Display.....	16
Chapter 3 Installation.....	19
3.1 Open the Package and Check.....	20
3.2 Environmental requirement.....	21
3.3 Install the Monitor .....	21
3.4 Connect the Power Cables.....	22
3.5 Power on .....	23
3.6 Power off.....	25
Chapter 4 System Menu.....	26
4.1 Patient Information Setup.....	26
4.2 Default setup.....	28
4.3 Trend Review, Measurement Review and Alarm Event Review .....	29
4.4 System setup.....	29
4.5 Machine version.....	38
4.6 Drug calculation .....	38
4.7 Maintain .....	38

4.8	Demo.....	44
Chapter 5	Alarm .....	45
5.1	Alarm classification .....	45
5.2	Alarm level .....	46
5.3	Alarm mode .....	47
5.4	Alarm setup.....	48
5.5	Alarm status .....	51
5.6	Measures for Alarm occurs .....	53
5.7	Probe-off alarm .....	53
Chapter 6	Freeze .....	54
6.1	Enter/Exit Freeze Status.....	54
6.2	FREEZE Menu .....	55
6.3	Reviewing Frozen Waveform.....	55
6.4	Recording Frozen Waveform.....	56
Chapter 7	Recording.....	57
7.1	General Information for Recorder.....	57
7.2	Recording Type.....	57
7.3	Recording Start&Stop.....	61
7.4	Recorder Operations and Status Messages .....	62
Chapter 8	Recall .....	64
8.1	Trend Graph .....	64
8.2	Trend Table.....	67
8.3	NIBP recall .....	69
8.4	Alarm recall .....	69
8.5	SD recall.....	71
Chapter 9	Drug Calculation and Titration Table.....	78

9.1	Drug Calculation.....	78
9.2	Titration Table .....	80
Chapter 10	ECG Monitoring .....	82
10.1	Introduction .....	82
10.2	Safety information.....	82
10.3	Monitoring Procedure.....	84
10.4	ECG Screen Hot Keys.....	90
10.5	ECG setup.....	92
10.6	ECG Alarm and Prompt Message .....	96
10.7	ST Segment Monitoring .....	97
10.8	ARR Monitoring.....	101
Chapter 11	RESP Monitoring.....	109
11.1	Introduction .....	109
11.2	Safety information.....	109
11.3	Placement for RESP electrode .....	109
11.4	RESP SETUP .....	110
11.5	RESP Alarm message.....	111
Chapter 12	SpO <sub>2</sub> Monitoring.....	113
12.1	Introduction .....	113
12.2	Safety information.....	114
12.3	SpO <sub>2</sub> Measurement.....	115
12.4	Monitoring steps.....	116
12.5	Measurement Limitations.....	117
12.6	SpO <sub>2</sub> SETUP .....	118
12.7	SpO <sub>2</sub> Alarm message.....	119
Chapter 13	NIBP Monitoring.....	122

13.1	Introduction .....	122
13.2	Safety information.....	122
13.3	Measurement Limitations.....	124
13.4	Measurement steps .....	125
13.5	Operation hints .....	126
13.6	Amend results .....	127
13.7	NIBP display.....	127
13.8	NIBP SETUP .....	128
13.9	NIBP Calibration .....	134
13.10	NIBP Alarm Message.....	134
Chapter 14	TEMP Monitoring .....	139
14.1	Introduction .....	139
14.2	Safety information.....	139
14.3	Measurement .....	139
14.4	TEMP SETUP.....	140
14.5	TEMP Alarm message .....	140
Chapter 15	IBP Monitoring .....	143
15.1	Introduction .....	143
15.2	Safety information.....	143
15.3	Monitoring Procedure.....	144
15.4	Setting for label name.....	145
15.5	IBP Menu.....	145
15.6	IBP Scale Setup.....	147
15.7	IBP Pressure Zero .....	147
15.8	IBP Calibration.....	149
15.9	Troubleshooting for Pressure Calibration .....	151

15.10	Alarm Information and Prompts .....	151
Chapter 16	CO <sub>2</sub> Measuring .....	156
16.1	Introduction .....	156
16.2	Safety information.....	157
16.3	Monitoring steps.....	157
16.4	CO <sub>2</sub> Menu.....	161
16.5	Influence factors .....	164
16.6	Alarm Information and Prompts .....	164
Chapter 17	Battery .....	168
17.1	Introduction .....	168
17.2	Battery status information .....	168
17.3	Battery installation .....	168
17.4	Check for battery performance .....	169
17.5	Battery maintenance.....	171
17.6	Battery recycle .....	171
Chapter 18	Maintenance and Cleaning .....	172
18.1	Introduction .....	172
18.2	Cleaning .....	172
18.3	Disinfection .....	176
Chapter 19	Maintenance .....	177
19.1	Check.....	177
19.2	Troubleshooting .....	178
19.3	Maintenance plan .....	180
19.4	NIBP CALIBRATE .....	181
19.5	ECG Calibration .....	182
Chapter 20	Accessories.....	183

20.1	ECG Accessories .....	183
20.2	SpO <sub>2</sub> Accessories .....	184
20.3	NIBP Accessories .....	185
20.4	TEMP Accessories .....	186
20.5	IBP accessories.....	186
20.6	CO <sub>2</sub> Accessories.....	187
Chapter 21	Default Settings .....	189
21.1	Country-Specific Default Settings .....	189
21.2	Alarm and Measurement Default Settings.....	199
Appendix A	Product Specification.....	205
Appendix B	EMC Test Level Declaration – Guidance and Manufacture's Declaration.....	220
Appendix C	System Alarm Prompt .....	227
Appendix D	SpO <sub>2</sub> Clinical Information.....	236
Appendix E	Abbreviations .....	238

## Chapter 1 Safety

### 1.1 Safety information

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#### WARNING

- Before using the device, the equipment, patient cable and electrodes etc. should be checked. Replacement should be taken if there is any evident defect or signs of aging which may impair the safety or performance.
- The Monitor is intended for clinical monitoring application with operation only granted to appropriate medical staff.
- The monitor can be used on only one patient at a time.
- EXPLOSION HAZARD-Do not use the device in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.
- There could be hazard of electrical shock by opening the monitor casing. All servicing and future upgrading to this equipment must be carried out by personnel trained and authorized by our company.
- To prevent delayed treatment, sufficient alarm setup should be done according to individual patient situation and make sure that alarm sound can be activated when alarm occurs.
- Do not touch the patient, table, or the device during defibrillation.
- The device is available to connecting with the patient who using cardiac pacemaker or other electrical stimulation devices, but this may result in risks.
- When used with Electro-surgery equipment, the operator (doctor or nurse) must give top priority to the patient safety.
- The monitor and devices connected to it shall form an equipotential system (protective earthing).

- If the protective earthing system is unstable, the monitor should apply internal power supply.
  - This device can only be connected to a power socket with protective earthing. If the power socket is not grounded, do not use the socket and the monitor should be power supplied by rechargeable batteries. Do not connect the three-wire cable to a second-wire plug.
  - The information of physiological waveform, physiological parameters and alarm, etc., shown on the monitor is for medical reference only, it can not be regarded as the basis for clinical treatment directly.
  - Be careful to place the power cord and various cables of accessories to avoid the patient being wound or suffocated, or the cable entangled together, or subject to electrical interference.
  - The disposal of scrap device, its accessories and packaging should follow the local laws and regulations, to avoid polluting to the local environment. And the packaging materials must be placed in the region where the children are out of reaching.
  - Do not modify the monitor and its accessories without SINKO's authorization. This could lead to unknown danger, compromising electrical safety, change in device performance, or changes in device capabilities that may cause harm for patient and/or operator.
-

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## CAUTION

- The monitor's service life is 5 years. At the end of its service life, the product described in this manual, as well as its accessories, must be disposed in compliance with related local regulations or hospital regulations. If you have questions concerning disposal of the product, please contact our company or representative institution.
  - When you have questions about the integrity of the external grounding of the monitor and its arrangement, the internal battery must be used for operation.
  - Electromagnetic fields can affect the performance of the monitor, so other equipment used near the monitor must meet the appropriate EMC requirements. Mobile phones, X-rays, or MRI devices are possible sources of interference because they could emit high-intensity electromagnetic radiation.
  - Before turning on the power to the device, make sure that the supply voltage and frequency match the device's label or the requirements specified in this manual.
  - When the battery is about to exceed its service life, remove the battery immediately from the monitor.
  - To ensure patient safety, please use the accessories specified in this manual.
- 

### NOTE:

- Install the equipment in a location that is easy to observe, operate and maintain.
- If the monitor gets damp accidentally, or the liquid is dumped on the equipment or accessories, especially if the liquid is likely to enter the monitor, please contact the service personnel in time.

- The software is developed in accordance with IEC62304. The possibility of risks caused by program error has been minimized.
- The pictures and interfaces in this manual are for reference only, please in kind prevail.

## 1.2 Precautionary measures

- In order to avoid the accumulation of electrostatic charge, it is recommended to store, maintain and use the equipment at a relative humidity of 30% or more. The floor should be covered with ESD dissipated carpets or similar materials. In the use of the components, non-synthetic clothing should be worn.
- In order to prevent electrostatic discharging to the ESD-sensitive parts of the device, the personnel should contact the metal frame of the components or the large metal objects near the device. When using the device, especially when it is possible to contact the ESD-sensitive parts of the device, the operator should wear a grounded bracelet designed for ESD-sensitive devices. For more information on proper use, please refer to the instructions provided with the bracelet.

## ESD Precautionary procedure training

- All potential users are advised to understand the ESD warning symbols and receive training on ESD precautions.
- The most basic content of the ESD precautionary procedure training should include an introduction to electrostatic charge physics, voltage level in the conventional case, and damage to the electronic components when the operator with electrostatic charge contacts them. In addition, the methods for preventing electrostatic buildup, and the manner and reasons for the

release of human body static electricity to the ground or equipment frame or the use of a bracelet to connect the human body to the equipment or the ground before establishing the connection should be described.

### 1.3 Symbols

Your device may not contain all the following symbols.

	Attention! Please read the accompanying file (the user manual).		
	Danger of electrocution, 220V supply mains.		
	Attention! Please read the accompanying file (the user manual).		Manufacturer
	Battery		Use by
	Alternating current		This way up
	Direct current		Fragile, handle with care
	Standby		Keep dry
	USB port		Stacking layers limit
	Equipotential		Atmospheric pressure limitation
P/N	Part number		Temperature limitation

<b>LOT</b>	Batch code		Humidity limitation
<b>SN</b>	Serial number		Internet access
	Date of manufacture		Latex free
	Waste disposal mark, this symbol indicates that the waste of electrical and electronic equipment can not be disposed as an unclassified municipal waste and must be recovered separately.		
	This symbol indicates that the applied part belongs to type BF, also the unit contains type F isolated (floating) applied part, and it has defibrillation proof function, but does not include direct cardiac application.		
	This symbol indicates that the applied part belongs to type CF, also the unit contains type F isolated (floating) applied part, and it has defibrillation proof function, but does not include direct cardiac application.		

## **Chapter 2 General**

### **2.1 Introduction**

Structure and composing: main unit, accessories (ECG lead cables, SpO<sub>2</sub> sensor, NIBP extension tube, NIBP cuff, TEMP probe, etc.) and power cord.

The monitor is applicable for the clinical monitoring of adult, pediatric and neonate(SpO<sub>2</sub> function is inapplicable on neonate in American). Physiological parameters including ECG (including ST-segment measurement and arrhythmia analysis), RESP, SpO<sub>2</sub>, PR, NIBP, TEMP,IBP and CO<sub>2</sub>, can be monitored. The monitoring information could be displayed, reviewed and printed.

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#### **WARNING**

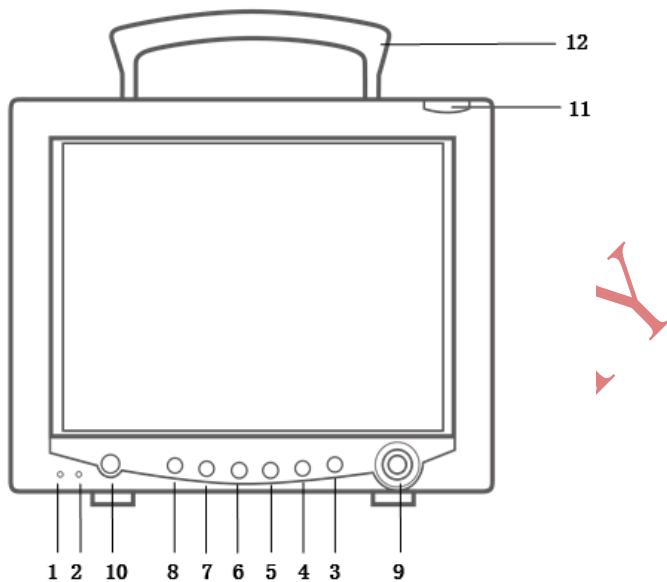
- The monitor should be used by a qualified clinician or under the guidance of a professional clinician. Personnel who uses this monitor should be adequately trained. The personnel without authorized or who are not trained, shall not carry out any operation.
- 

### **2.2 Contraindications**

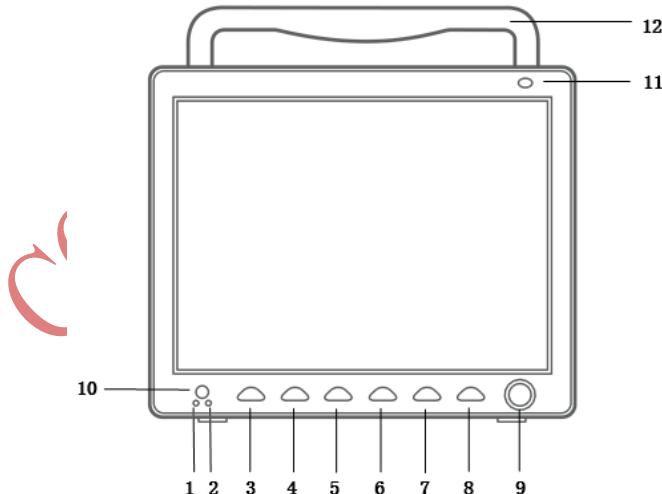
Prolonged use of sensors and electrodes (ECG electrode, NIBP cuff, SpO<sub>2</sub> sensor) on patient's body might cause skin rash and discomfort.

### **2.3 Main unit**

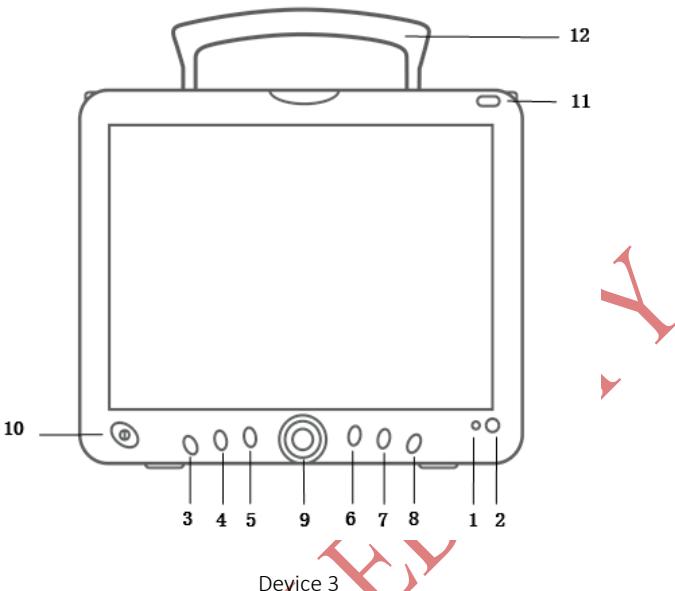
Front view



Device 1



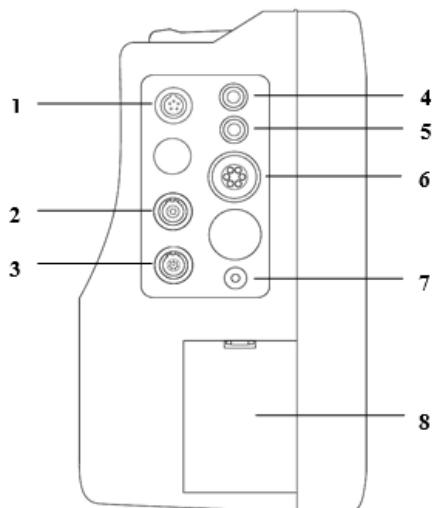
Device 2



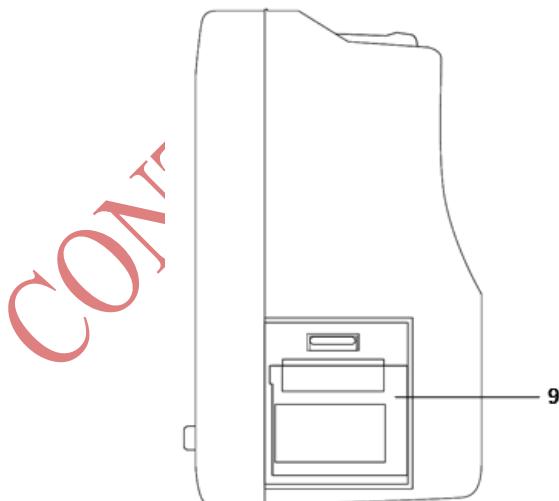
Device 3	
1	AC indicator: On: the monitor is connected to AC power supply; Off: the monitor is disconnected from AC power supply.
2	Battery status indicator: it displays green and flickers under battery-powered condition, it always displays orange in charging state and green after fully charged. Or Running indicator: when the device turns on, this indicator will be lighting, when it turns off, this indicator will go out. Please make the object as the standard.
3	MENU: Press this button to call up the SYSTEM MENU, in which the user may set up system information and perform review operation.
4	NIBP: Press it to inflate the cuff to start a blood pressure measurement. When measuring, press it to cancel the measurement and deflate the cuff.

5	<b>REC/STOP:</b> Press it to start a real time recording. The recording time can be set in "RT REC TIME" item under "RECORD" menu.
6	<b>SILENCE:</b> Push this button to suspend the alarm (with 1 minute and 2 minutes selectable), and a  symbol appears in the alarm area. Push this button for more than 1 second to mute all kinds of sounds (including alarm sound, heart beat, pulse tone, key sound). At the same time, a  symbol appears. Push this button again to restore all kinds of sounds and the  symbol disappears from the screen.
7	<b>FREEZE:</b> Freeze or unfreeze the waveform
8	<b>MAIN:</b> Whatever levels of menu the system is in, press the button and the system will always return to the main screen.
9	<p>Rotary knob</p> <ul style="list-style-type: none"> <li>◆ Rotating: clockwise or counter-clockwise rotating to move the cursor</li> <li>◆ Pressing: press the knob to execute certain operations, such as entering a menu or processing a command.</li> </ul>
10	<p><b>ON/OFF</b></p> <ul style="list-style-type: none"> <li>◆ ON: press this button to turn on the monitor</li> <li>◆ OFF: in turning on state, keep pressing this button for 3 seconds can turn off the monitor.</li> </ul>
11	Alarm indicator: indicating alarm level by different color and flicking frequency
12	handle

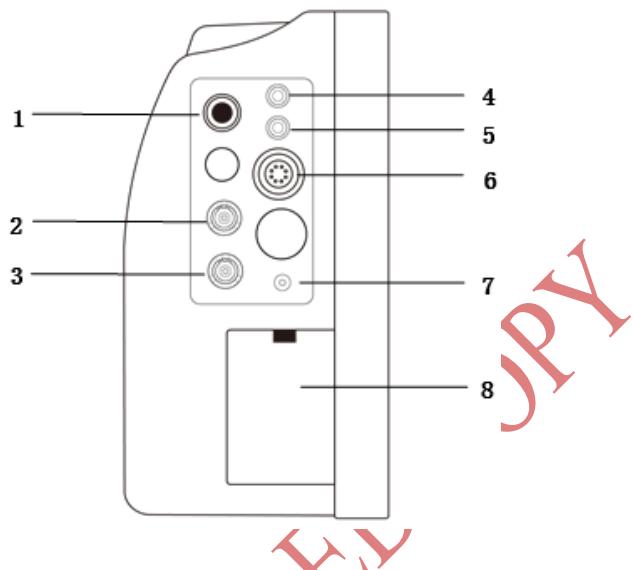
Side view



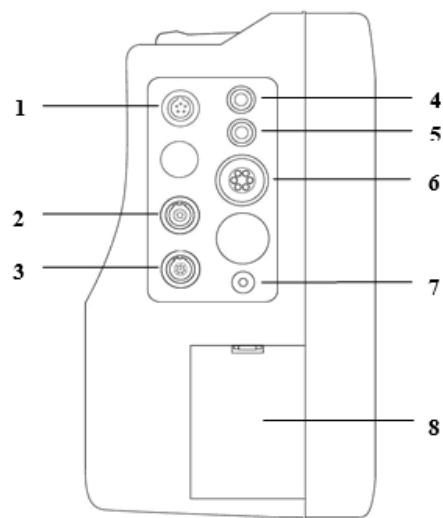
1 2 3 4 5 6 7 8



Device 1

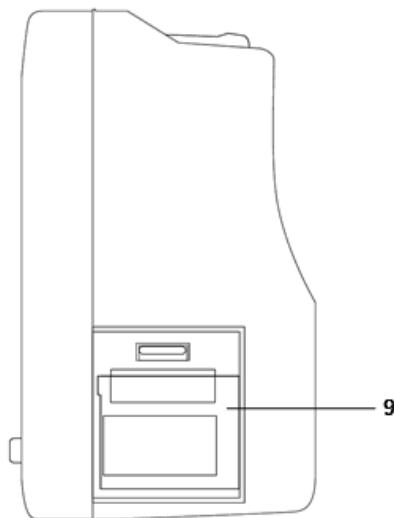


Device 2



OPY

EY

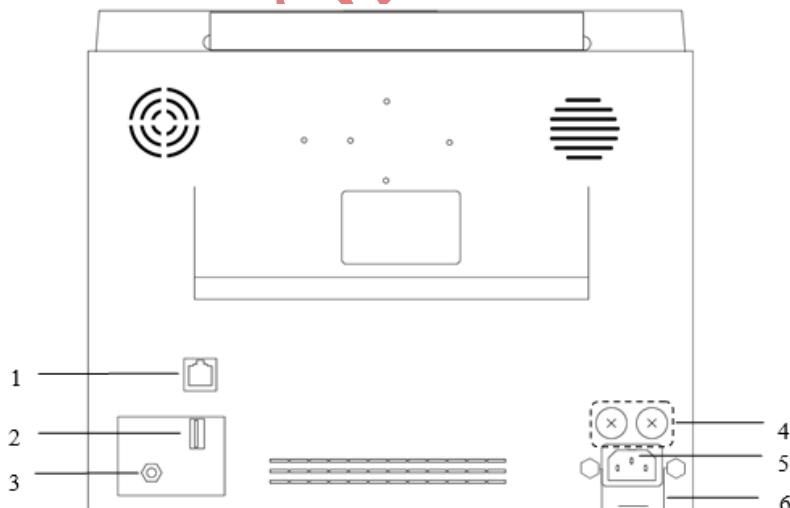


CON<sup>T</sup>

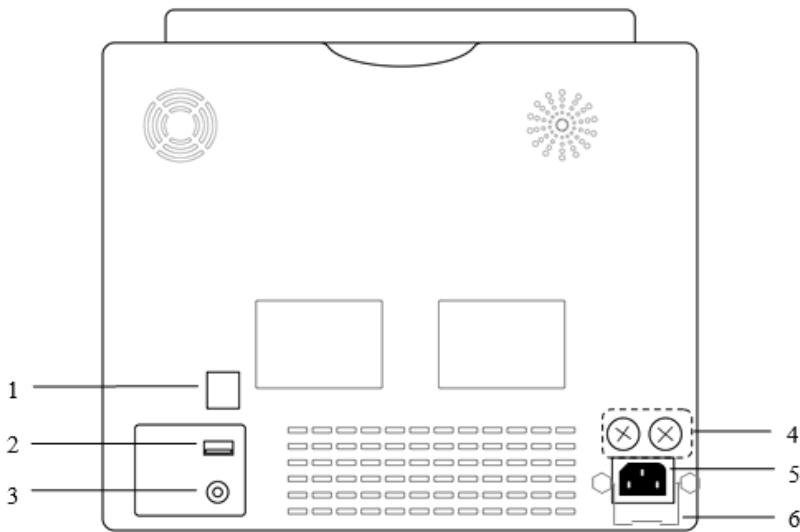
Device 3

<b>1</b>	SpO <sub>2</sub> : Socket for SpO <sub>2</sub> sensor
<b>2</b>	IBP: Socket for IBP module
<b>3</b>	CO <sub>2</sub> : Socket for EtCo <sub>2</sub> module
<b>4</b>	T1: Socket for channel 1 TEMP probe
<b>5</b>	T2: Socket for channel 2 TEMP probe
<b>6</b>	ECG: Socket for ECG cable
<b>7</b>	NIBP: Socket for NIBP cuff
<b>8</b>	Battery cover
<b>9</b>	Recorder

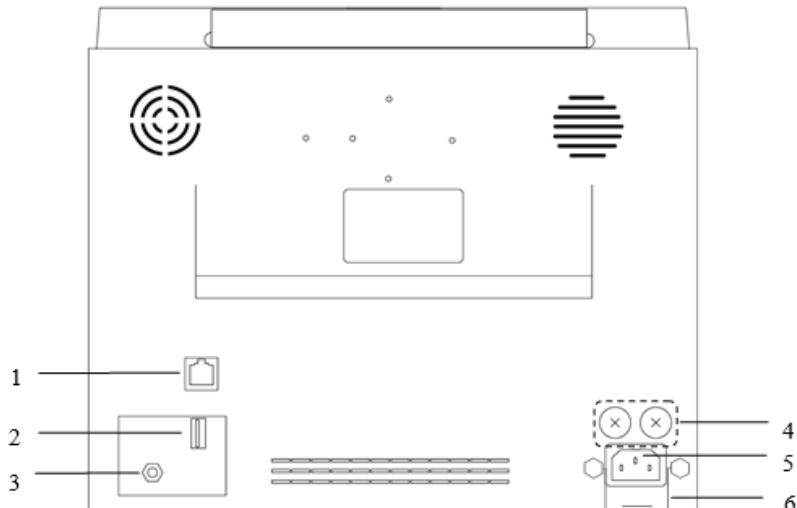
Rear view



Device 1



Device 2



Device 3

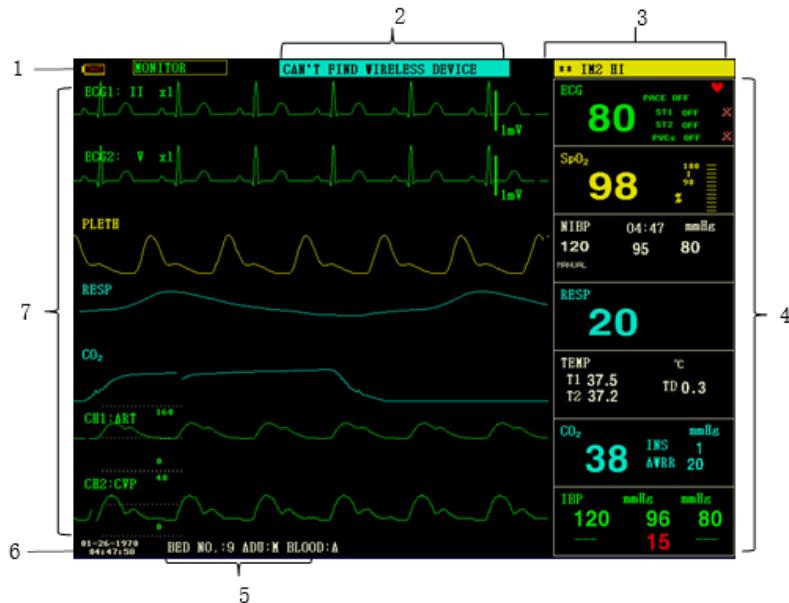
1	Network interface: standard RJ45 interface, connecting with the central monitoring system of our company by network cable
2	USB port: connecting with external memory devices
3	Equipotential grounding terminal: when the monitor is used together with other equipment, use a cable to connect other equipment to the equipotential terminal of the monitor, which eliminates the ground potential difference between the different devices to ensure safety.
4	Fuse: T1.6AL250V
5	AC power port
6	Lockage hook for power cord

**NOTE:**

- Replacement of fuse: unplug the power cord, then disassemble the screws by using tools.
- The network interface can only connect with the central monitoring system of our company to form a network monitoring system.

#### 2.4 Display

The monitor adopts high resolution color TFT LCD screen, which clearly displays all physiological parameters and waveforms of the patient. The following figure is a standard interface in normal monitoring state.



1. Battery indicator



The battery works normally, the solid part represents battery level.



Battery is low, it needs to be charged immediately, and the monitor generates low battery alarm.



The monitor does not contain internal battery.

2. Technical alarm area

Displaying technical alarms and prompt messages, cycle display for multiple pieces of information.

3. Physiological alarm area

Displaying physiological alarms, cycle display for multiple pieces of information.

4. Parameter area

Consisting of several individual areas, displaying the measured value

corresponding to each parameter module. The name of an individual parameter is on the top left of its area.

5. Patient information area

"BED NO.": Bed number of patient under monitoring

"PAT TYPE": Patient type of the patient under monitoring (adult, pediatric, neonates)

"SEX": Patient sex

"BLOOD": Patient blood type

6. Date and Time

Indicating current date and time, available to calibrated if necessary.

7. Waveform area

Mainly displaying the waveform of physiological parameters, the name of each waveform is on the top left.

ECG lead is selectable according to the demand. The filter mode is displayed at the top of screen. Gain of each channel is displayed above its waveform, at the right side of the waveform, there is a scale of one millivolt.

When a menu pops up in the interface, it always locates a fixed area in the middle of the waveform area, which will cover parts of the waveform, while the waveform will appear after exit the menu.

The waveform is refreshed at a certain speed, the speed adjustment please refer to the setup of each parameter.

## Chapter 3 Installation

The portable monitor is designed to comply with relevant safety requirements of IEC 60601-1, IEC 60601-2-27 and IEC 80601-2-30 for medical electrical equipment. The system has a floating input for defibrillation proof and electrosurgical knife protection. If the correct electrodes (see the section about ECG Monitoring) are used and placed according to the manufacturer's instructions, the display will be restored within 5 seconds after defibrillation.

---

### WARNING

- If any sign of damage to the monitor function is detected, or an error message appears, do not use it on any patient. Contact biomedical engineer in the hospital or our maintenance engineer immediately.
- All analog and digital equipment connected to this device must be certified by specified IEC standards (e.g. IEC 60950 and IEC 60601-1), and all equipment shall comply with the requirements of IEC 60601-1-1 (valid versions) for connection. The person who connects the additional equipment to the input/output port, is responsible for the compliance with the IEC 60601-1-1 standard. If you have any questions, please contact us.
- When this device is connected to other electrical equipment in order to achieve a specific function, if the hazards of this combination can not be determined from the specifications of each equipment (for example, the risk of electric shock due to the accumulation of leakage current), please contact our company or experts in the hospital related this field to ensure that the necessary safety of all equipment in this combination will not be damaged.
- Please use our designated bracket (optional). When installing the bracket,

please avoid the screws to touch the circuit board inside the machine.

---

**NOTE:**

- To ensure the monitor works normally, please read this chapter and the content about patient safety before use, and follow the requirements for installation.
- If the monitor finds any fatal error during self-test, it will alarm.
- Keep the package and packing materials for possible future transportation or storage.

### 3.1 Open the Package and Check

Before opening the package, please check it carefully. If any damage is found, please contact the carrier immediately.

Open the package and take out the monitor and accessories carefully. Check the components according to the packing list to see whether the device has any mechanical damage or any part is missing. If there is any problem, contact the our company immediately.

---

#### **WARNING**

- The disposal of packaging materials should obey the local regulations or the hospital waste disposal system. The packaging material must be keep out of the reach of children.
- The device may get biological contaminated during storage, transport or use. Please confirm that the package is intact before use, especially the disposable accessories. If any damage is found, please don't put it into use.

---

**NOTE:**

- Keep the package and packing materials for possible future transportation or storage.

### **3.2 Environmental requirement**

Please obey the following instructions to ensure the safety of electrical installation. The environment for potable monitor using shall properly away from vibration, dust, corrosive or flammable gas, extreme temperature or humidity and so on. When it is installed in a cabinet, there should be enough space in front of the device for convenient operation. When the door of the cabinet is opening, enough space at the back of the device should be guaranteed for convenient maintenance. Allow at least 2 inches (5 cm) of space around the instrument to ensure air circulation.

---

#### **WARNING**

- The environment for use, storage and transport should meets the requirements described in this manual, otherwise the specifications of this product stated in this manual may not be able to achieved, or even cause damage to the device.
- 

Make sure that the device is free from condensation during working, when it is carried from one room to another room, condensation may appears. This is because it is exposed under humid air with different temperatures.

### **3.3 Install the Monitor**

If everything goes well, please place the monitor on a flat surface or fix it on the wall. The installation of wall bracket please refer to its instructions.

#### **3.3.1 Place on a Flat Surface**

Place the monitor on a flat surface. The surface should be away from vibration, dust or corrosive drugs.

### **3.4 Connect the Power Cables**

Please use the power cord equipped for the monitor. Plug the power cord to the power port on the monitor, and another end to a grounded three-core power socket.

If the monitor is equipped with an adopter, plug one end of the adopter to the power port on the monitor, and another end to a grounded three-core power socket.

#### **NOTE:**

- **Plug the power cord to the hospital outlet. If necessary, connect it with the equipotential ground wire.**
- **When the device is equipped with battery, it must be charged after transport or storage. If turn on the device directly without connecting with AC power supply, it may not work normally due to lack of electricity. The device can be charged after connecting with the AC power no matter it is turned on or not.**

#### **Ground**

In order to protect patients and medical personnel, the enclosure of portable monitor must be grounded. Therefore, the portable monitor is equipped with a removable three-wire cable, when it is inserted into a matching three-wire socket, the device will be grounded through the ground wire in the power cord. If there is no three-wire socket, consult the hospital's electrical management staff.

---

#### **WARNING**

- **Do not insert the three-core wire into a two-core socket.**
- 

Connect the equipotential grounding terminal on the device to the grounding wire. If the hazards of a specific combination can not be determined from the specifications of each equipment (for example, the hazard caused by

accumulation of leakage current), please contact the manufacturer or experts related this field to ensure that the necessary safety of all equipment in this combination will not be damaged.

### **Equipotential ground**

The room protective grounding system is realized by power plugs grounding, it already includes the primary protection of the device. For internal examination of the heart or brain, the portable monitoring system must be individually connected to the equipotential grounding system. One end of the equipotential grounding wire (potential equalization wire) is connected to the equipotential grounding terminal on the rear panel of the device and the other end is connected to a connector of the equipotential system. If the protective grounding system is damaged, the equipotential grounding system undertakes the safety function of protecting the grounding wire. The examination of the heart (or brain) should only be carried out in a medical room with a protective grounding system. Before each use, check whether the device is in good working condition. The cable connecting the patient and the device must be free from electrolyte contamination.

## **3.5 Power on**

### **3.5.1 Device inspection**

#### **1. Appearance inspection**

Appearance inspection for the installed monitoring system:

- Carefully check the patient monitor for any mechanical damage.
- make sure the monitor is correctly installed according to the specified installation program.
- Make sure the cables connecting patient monitor and external equipment are undamaged, and connected to corresponding interfaces correctly.

- Make sure the external module is connected correctly.
- Make sure the battery cover is installed.

The chapter *Maintenance and Cleaning* provides detailed information about the cautions, requirements of cleaning, cleaning procedure and recommended cleaning agent.

## 2. Functional inspection

### ■ Start

- 1) Plug the power cord to the AC power port. If the device uses internal battery for power, please make sure that there is enough battery power in the battery.
- 2) Turn on the patient monitor, it should start normally:
  - The red and yellow alarm lamp respectively light.
  - The system beeps for each time of powering on, and the LED indicator on control panel or the screen flickers once. If no beep sound or flickering, please stop using this monitor, and contact our company for maintenance.
  - There are no error messages appear on the screen.
- 3) Check all functions that the patient may need to ensure the device could work normally.

---

### WARNING

- When the monitor is powered on, the system will check whether the alarm function (audio and light alarms) is normal. If the alarm function works abnormally, this monitor can not be used for patient monitoring and contact the manufacturer's maintenance department.
- 

### NOTE:

- Charge the battery to full for the first time of use. Keep the monitor connecting with main power supply before the battery is fully charged.

- Display

- 1) Ensure that all text are readable, and all images are clear.
  - 2) Ensure that the device brightness is normal.

- Main unit

Check whether the time displayed on screen is correct. If necessary, please adjust its time and date.

- Check the Recorder

If your monitor is equipped with a recorder, open the recorder door to check if paper is properly installed. If it is out of paper, refer to the chapter *Recording* for details.

### 3.5.2 Start monitoring

1. Check whether the patient cables and sensors are correctly connected.
2. Check whether the settings of the monitor are correct, such as "PAT TYPE" and "Pacemaker".
3. For the detailed information about the measurement and monitoring of each parameter, please refer to relevant chapter.

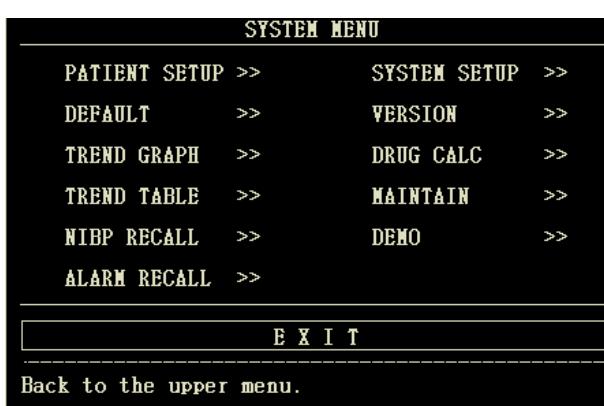
### 3.6 Power off

Turn off the monitor according to the following steps:

1. Unplug the cables and sensors connecting with the patient.
2. Keep pressing ON/OFF button for 3 seconds to turn off the monitor.

## Chapter 4 System Menu

This monitor features flexible configurations. You can customize monitoring content, waveform sweep speed, sound volume, and output content. Press the MENU button on the front panel of the monitor, the interface shown in the following figure will appear:



### 4.1 Patient Information Setup

Select the "PATIENT SETUP" item in the "SYSTEM MENU", the following patient information can be set by user:

- DEPT.: the department that the patient receives treatment
- PAT NO.: case number of the patient
- BED NO.: selectable from 1~100
- DOCTOR: name of the attending doctor
- NAME: patient's name (Valid characters: a~z, A~Z, 0~9, and the space, 12 characters can be input at most)
- SEX: patient's gender (female, male)
- PAT TYPE: patient type (adult, pediatric, neonate)

ADMIT: date of admission (format: year/month/day)

BIRTH: patient date of birth (format: year/month/day)

HEIGHT (cm/inch): patient's height (turning the knob with the increase/decrease of 0.5 cm/inch each time), the unit of height in other menus accord with the unit set here.

WEIGHT (kg/lb): patient's weight (turning the knob with the increase/decrease of 0.5 kg/lb each time), the unit of weight in other menus accord with the unit set here.

BLOOD: blood type of the patient ((Available options: A, B, AB, O, N, "N" means unknown blood type)

SAVE: to save the changes of patient information, corresponding information will be displayed in Patient information area

DELETE: to delete the information of current patient, and to register a new patient

After clicking the "DELETE" button in this menu, a dialog box "CONFIRM TO DELETE" will pop up, you could select "YES" or "NO" to decide whether to clear current patient information.

**NOTE:**

- If you choose "YES", the information of current patient will be deleted.
- Please click "SAVE" button if the information of current patient is changed, otherwise the changes will be invalid.

## 4.2 Default setup

### NOTE:

- After selecting any item in this sub-menu, the selected item will replace the current setup of the system and accordingly become the system default configuration.



In this sub-menu, you can select both the factory default and the user-defined default. Also in this sub-menu, you can save the current system configuration as the user-defined default configuration. But at this time, the system will automatically save all the setups in the parameter menu, ECG gain and filter way as the user-defined default configuration according to the patient type. Also, a dialog box "CONFIRM TO SAVE" will pop up.

Select "YES" to save all configurations of current patient type as user-defined default configuration.

Select "NO" to give up the modification and the system will keep the previous configuration.

### NOTE:

- After selecting any item in the "DEFAULT" menu and exiting the dialog box, the "CONFIRM TO SAVE" dialog box will pop up, in which you can select "YES" to confirm your selection or "NO" to give up your selection.

#### 4.3 Trend Review, Measurement Review and Alarm Event Review

In the "SYSTEM MENU", there are "TREND GRAPH", "TREND TABLE", "NIBP RECALL" and "ALARM RECALL" items. Please refer to *Chapter 8 Recall* for detailed information.

#### 4.4 System setup

Select the "SYSTEM SETUP" item in the "SYSTEM MENU", the following menu will appear:



In the "SYSTEM SETUP" menu, user can set the following items.

##### 4.4.1 Face select

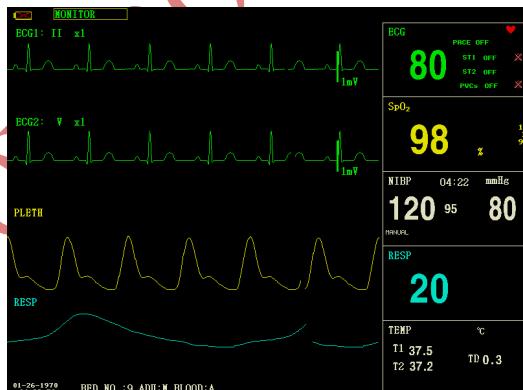
The system provides 5 display modes: "STAND SCREEN", "OxyCRG SCREEN", "TREND SCREEN", "BIG CHAR" and "VIEWBED SCREEN". You can choose any one of them according to clinical demand.

Select the "FACE SELECT" item in the "SYSTEM SETUP" menu to enter the following menu:



### 1. STAND SCREEN

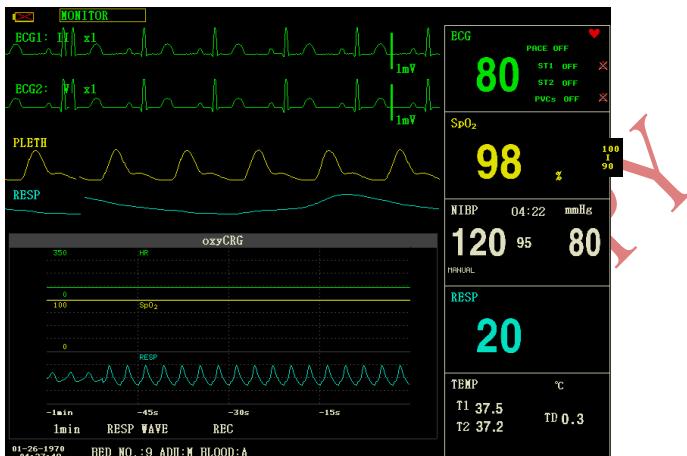
The "STAND SCREEN" is the default setting. If the current screen is not the standard screen, you may enter the standard screen by selecting "STANDARD SCREEN" and then selecting "EXIT" in FACE SELECT menu.



Stand Screen

## 2. OxyCRG SCREEN

If you want to enter the following interface, select "OxyCRG SCREEN" and then select "EXIT" in "FACE SELECT" menu.



OxyCRG Screen

OxyCRG screen is located at the lower part of the waveform area, consisting of the HR trend, the SpO<sub>2</sub> trend, and the RR (respiration rate) trend or the compressed RESP waveform. Below the RR trend or the compressed RESP waveform is the scale of the trend time. In addition, three labels are displayed beneath the time scale. The labels are detailed as below.

①. Trend length

This label allows you to select the time duration of the trend graphs displayed.

You can select either 1 min, 2 min or 4 min.

②. Compressed RESP waveform/RR trend

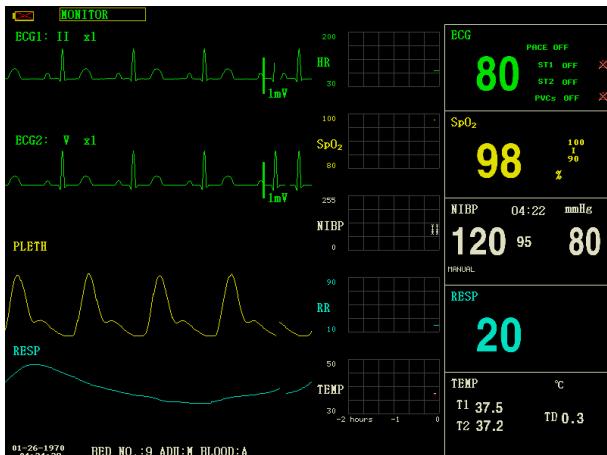
With this label, you can select to display the compressed respiration waveform or the RR trend. You can select either RESP WAVE or RR.

③. Recording

You can select the REC label to print out the trend or the waveform displayed in the oxyCRG screen.

### 3. TREND SCREEN

If you want to enter the following interface, select "TREND SCREEN" and then select "EXIT" in "FACE SELECT" menu.



Trend Screen

- Trend graph

In the waveform area, the trend graph is located on the right side of the corresponding waveform, displaying the trends of one parameter of each module. The parameter labels, as well as their scales, are displayed on the left of the trend graph.

- Trend length

The trend length, located below the trend graph, is 2 hours. In the trend graph, the scale reading at the right end of X-axis is 0 hour, the reading at the left end is -2 hours.

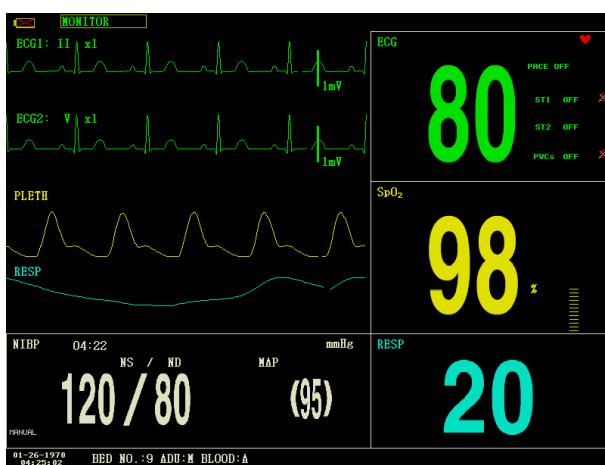
- Selecting a trend parameter

If a module has multiple trend parameters, you can select one from the

parameter label options of the corresponding trend graph. The trend graph of the selected parameter will be displayed. For example, in the ECG trend graph, you can select either from the parameter label options: HR, ST, PVCs.

#### 4. BIG CHAR

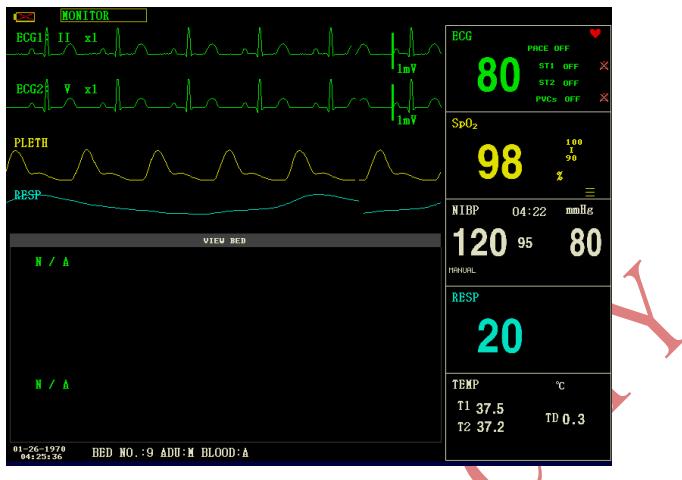
To view the parameter more clearly in a long distance.



Big Char

#### 5. VIEWBED SCREEN

This monitor can display one parameter waveform and all measured data from another patient monitor in the same monitoring network system. To enter the following screen, open "FACE SELECT" menu, select "VIEWBED SCREEN" item, and then select "EXIT".



Viewbed Screen

The monitor that used to view the situations of other monitors, is called "host monitor". The monitor being viewed is called "viewbed monitor". The viewbed screen is always displayed at the lower part of the host monitor's waveform area. It consists of the following parts.

① Viewbed monitor label

The viewbed monitor label allows you to select the viewbed monitor you want to view. It displays the bed number and patient's name of the viewbed monitor.

② Viewbed parameter area

All parameter data of the viewbed monitor is displayed in this area.

③ Viewbed waveform label

The viewbed waveform label allows you to select a waveform of the viewbed monitor.

④ Viewbed waveform area

The viewbed waveform area is located beneath the viewbed waveform label. It

displays the waveform selected through the viewbed waveform label. The scanning speed is 25 mm/s. In addition, information relating to the viewbed waveform is shown above the waveform.

#### 4.4.2 Wave setup

1. Select "WAVE SETUP" item in the "SYSTEM SETUP" menu.
2. Adjust the wave type of a channel, the wave corresponding to this channel in the main interface will change accordingly.

#### 4.4.3 Wave select

1. Select "WAVE SELECT" item in the "SYSTEM SETUP" menu.
2. The waveform in waveform area will show up or disappear accordingly by selecting corresponding parameter or canceling the selection. The parameter in gray is unadjustable.
3. If "FULL ECG" is selected, the full-lead ECG waveform will be displayed in the waveform area in one screen, if "STEP ECG" is selected, the step ECG waveform will be displayed in the waveform area.

#### NOTE:

- "FULL ECG" and "STEP ECG" are set off as default, and these two functions can not be turned on at the same time.

#### 4.4.4 Parameter setup

1. Select "PARAM SETUP" item in the "SYSTEM SETUP" menu.
2. You can set the font color in parameter area and the color of waveform.  
The color of parameter value activating the alarm is red.

#### 4.4.5 Parameter select

1. Select "PARAM SELECT" item in the "SYSTEM SETUP" menu.
2. The waveform and parameter will show up or disappear accordingly by selecting corresponding parameter or canceling the selection.

#### **4.4.6 Time setup**

1. Select "TIME SETUP" item in the "SYSTEM SETUP" menu.
2. You can set the "Date" and "Time" items. Use cursor to highlight the item that you want to modify and turn the knob to select time.
3. Then select "SAVE SET" button.

##### **NOTE:**

- The system time shall be set when turning on the monitor (if you need to set the system time); otherwise, when you review the content containing time information, the system may not display the correct time.

#### **4.4.7 Alarm setup**

Please refer to the sections about "Alarm".

#### **4.4.8 Record setup**

Select the "RECORD" item in the "SYSTEM SETUP" menu to pop up the following menu:

- REC WAVE1/REC WAVE2: The recorder could output up to 2 channels of waveform at a time. You can select the name of the waveform at the right column for "REC WAVE1" and "REC WAVE2". If you select "OFF", the waveform in this channel will not be output. These settings is applicable for real-time recording and timing recording.
- RT REC TIME: This item has two options, CONTINUAL and 8 s. "CONTINUAL" means once pushing the "REC/STOP" button on the recorder module or the monitor panel, the recorder will continuously print out the waveform or parameter until this button is pushed again.
- TIMING REC TIME: It represents the time interval between two recordings. Ten selections are available: "OFF, 10min, 20min, 30min, 40min, 50min, 1HOUR, 2HOURS, 3HOURS and 4HOURS". The system will start the recording

process according to the selected time interval. The recording time is always 8 seconds.

- REC RATE: This item has two options, 25.0mm/s and 50.0 mm/s.
- REC GRID: It is used to determine output format: OFF is without grid, and ON is with grid.
- CLEAR REC TASK: When too many recording tasks existing, you can use this function to clear the alarm event that has been generated and is waiting for outputting.

**NOTE:**

- The setup of "RT REC TIME" takes priority over the "TIMING RECTIMING".
- The recorder is a optional component.
- If two same waveforms are selected, the system will automatically change one of the waveform to a different one.

#### **4.4.9 Event setup**

In the process of monitoring a patient, the occurrence of some events may have impacts on the patient, resulting in some changes on the waveform or parameters. To analyse these effects, you can manually mark some specific events. The event will be displayed on the trend graph and trend table to assist the analysis of patient's parameters at the time of the event.

The monitor has four types of events. You can specify their representations by yourself.

Select the "MARK EVENT" item in the "SYSTEM SETUP" to modify the events.

How to mark the event:

1. Use the rotary knob to select one from event A, B, C and D.
2. The @ symbol will appear in the front of the event being selected.
3. Once making a wrong selection, you can push the knob on the event

again to give up the selection. Select "EXIT" to exit the menu and consequently the selection will come into effect.

#### 4.4.10 SD operate

Please refer to the chapter related to *SD Recall*.

### 4.5 Machine version

Select the "VERSION" item in the "SYSTEM MENU". In the popping up menu, you can learn the software version of the monitor.

Software name	CMS8000	CMS9000 (CMS7000)
Specification	None.	None.
Version	2.50311162128.66817	1.50311162128.66817
Naming standard	"Major adaptive upgrade", "Major enhancive software upgrade", "Major improvement software upgrade", "Minor corrective software upgrades", "Build"	

### 4.6 Drug calculation

You can use the drug calculation and titration table function of the monitor to calculate the concentration of 15 kinds of drugs. Refer to the *Chapter Drug Calculation and Titration Table* for detailed information.

### 4.7 Maintain

#### 4.7.1 User maintain

1. You need to select the "MAINTAIN" item in the "SYSTEM MENU", then select "USER KEY".
2. Input the password to enter the user maintain menu, then you can customize the maintenance settings. Items shown as below can be set:
  - LANGUAGE: select the language you need

- LEAD NAMING: AHA or EURO
- HELP SETUP: ON/OFF
- NIBP OBSTRUCT SETUP: 1/2/3/4

This function is used to detect whether the patient moves during the blood pressure measurement. If the patient moves, the monitor will give an alarm message and stop the current measuring, or the measurement will be taken as usual.

- 1) This function is set "1" as default.
  - 2) "1" represents the sensitivity is reduced to the minimum, "4" represents the sensitivity is increased to the maximum. The higher level the sensitivity is set and the easier to detect the interference of movement.
- "NETWORK CONFIGURATION": see *Section 4.7.3 Network Configuration* for details.
  - HL7 server configuration:
    - (1)IP: 202.114.4.120. Input the IP address of the server.
    - (2)Port: 511. Input the server port.
    - (3)Sending interval: 1. Set the frequency of data sending, unit is "second".
  - ALARM SET PASSWORD MODIFICATION: it is used to change the login password of "ALARM SETUP".

#### 4.7.2 Factory maintain

1. You need to select the "MAINTAIN" item in the "SYSTEM MENU", then select "FACTORY KEY".
2. Input the password to enter the factory maintain menu, this function is available for specific maintenance personnel of our company only.

#### 4.7.3 Network configuration

Click "NIT CONFIG" item, the following menu will pop up:



■ NET TYPE: CMS / CUSTOM

CMS:the Server IP is fixed, "202.114.4.119", "LOCAL IP CONFIG" is unavailable.

CUSTOM:when this item is selected, CMS and machine's IP can be changed as you need.The following is

"LOCAL IP SETUP"menu.

■ LAN CARD SET: 3G / Wireless / Wire

❖ 3G

It is strongly required to use the accompanying 3G bracket provided by manufacturer. CDMA2000 is appointed network, but WCDMA can be ordered.

NOTE:

● The monitor supports 3G, wireless and wire .

❖ Wireless

It is strongly required to use the accompanying wireless network card provided by manufacturer. The router complied with IEEE802.11 (ordinary or household wireless network router) should be used, and it shall support the authentication method of WPA, WPA2 or WEP. Wireless network router should access to the

Internet by WAN.

✧ **Wire**

The device has an interface for wire network mode, it accesses to wire LAN complied with IEEE802.3 by RJ45 connector. Wire network should access to the Internet by WAN of the router.

- NET TYPE: CMS or CUSTOM, select the network type according to your need

**CMS**

The Server IP is fixed "202.114.4.119". Once the monitor specifies the port number, the program will automatically obtain the local IP address and the port to be connected.

**CUSTOM**

In this mode, the IP address and subnet mask of the server, as well as the two items of this monitor can be set by user.

- LAN CARD SET: 3G/WIRELESS/WIRE

**3G**

The 3G network is mainly used to connect with the central monitoring system through the Internet WAN.

After selecting 3G network, restart the device, then the device will automatically obtain the WAN support (dynamic ip, DNS, etc.) from 3G card and its driver.

**NOTE:**

- The 3G mode is available only when the "NET TYPE" is "CUSTOM". If the monitor is connected to central station, the central station software need to be installed on a server with fixed IP address, this address shall be set in the "SERVER IP".

## WIRELESS

After selecting wireless network, click "SELECT ROUTE" in "NET CONFIG" menu, then click "SEARCH ROUTES". All searched routers will be listed on the screen, you can select one of them to connect as your need. If you choose a router set with secure connection, a dialog box will pop up for you to enter the password.



When the network type is CMS, just make sure the connection between the device and the wireless router is successful. (The IP address of the server is 202.114.4.119, the IP address of this monitor and subnet mask are generated by the port number.)

When the network type is CUSTOM, if DHCP service is used, the device will automatically obtain the network support (dynamic IP of this monitor, gateway, DNS, etc.) through the DHCP. If specified IP is used, please set the IP address of this monitor and subnet mask, click "LOCAL IP CONFIG" button, the following menu will pop up:



Back to the upper menu.

## Wire

When the network type is CMS, just make sure the connection between the device and the central station is successful. (The IP address of the server is 202.114.4.119, the IP address of this monitor and subnet mask are generated by the port number.)

When the network type is CUSTOM, make sure the monitor is connected to the router. If DHCP service is used, the device will automatically obtain the network support (dynamic IP of this monitor, gateway, DNS, etc.) through the DHCP. If specified IP is used, please set the IP address of this monitor and subnet mask.

- LOCAL NET NO: the physical bed number of the monitor
- SERVER IP: input the IP address or domain name of the server for central station software
- LOCAL IP CONFIG: when the "NET TYPE" is "CUSTOM", you can set the local IP address
- SELECT ROUTE: when the "LAN CARD SET" is set to "WIRELESS", click this button to enter the "SELECT ROUTE" menu, and start router searching and

other operations.

#### 4.8 Demo

Select the "DEMO" item in the "SYSTEM MENU" to enter the "DEMO KEY" dialog box. Input the password "2088", and click "CONFIRM" button, the system will enter DEMO status.

The demo waveform is an analog waveform set by the manufacturer only to show the performance of the machine and to train users.

In clinical application, this function is forbidden because it may mislead the medical staff to treat the DEMO waveform and parameters as the actual data of the patient, which may result in the delay of treatment or mistreatment. Therefore before entering this menu, you shall enter the password.

## Chapter 5 Alarm

When the patient being monitored appears abnormal changes in vital signs, or the monitor itself occurs failure and fails to monitor the patient, it will remind the medical workers through sound, light, etc.

---

### WARNING

- In any single area (e.g. intensive care unit or cardiac operating room), there is a potential hazard that the same or similar devices use different alarm preset.
  - When the monitor is powered on, the system will check whether the alarm function (audio and light alarms) is normal.
  - When turning on the monitor, the system will send a beep sound and the alarm light flickers once. This function is used to check whether the alarm function is normal. Therefore, user shall pay attention to these signs when turning on the device. If the alarm function works abnormally, this monitor can not be used for patient monitoring, please contact the manufacturer or the maintenance service center.
- 

### 5.1 Alarm classification

The alarm is classified as physiological alarm, technical alarm and prompt message based on the property of alarms.

#### 1. Physiological alarm

Generally, physiological alarm is activated in the following situations: one of the patient's physiological parameters exceeds the alarm limits, or the patient appears physiological abnormal, for example, HR exceeding the set limit. The information of physiological alarm is displayed in physiological alarm area.

## 2. Technical alarm

Technical alarm represents the alarms activated by abnormal monitoring or monitoring result distortion due to system failure, such as lead-off or low battery.

The information of technical alarm is displayed in technical alarm area.

## 3. Prompt message

Except the physiological alarm and technical alarm, these messages refer to the displayed information about system status, which are not involved with patient vital signs. Prompt messages are often displayed in technical alarm area. Besides, some prompt messages are displayed in parameter area, for example, the messages related to NIBP are displayed in NIBP area.

### 5.2 Alarm level

The alarm is classified as high-level alarm, medium-level alarm and low-level alarm according to its severity.

#### 1. High-level alarm

High-level alarm indicates the patient's life is in danger or the monitor under using has serious problem in technical respect. It is the most serious alarm.

#### 2. Medium-level alarm

Medium-level alarm means serious warning.

#### 3. Low-level alarm

Low-level alarm is a general warning.

#### NOTE:

- The level of all technical alarms and prompt messages and some of the physiological alarms are determined by the system, which can not be changed by user.
- The level of most of the physiological alarms need to be set by user, such as alarm limits.

### 5.3 Alarm mode

When alarm occurs, the monitor may draw the user's attention in three ways as below:

- Audio alarm
- Light alarm
- Alarm message

#### 5.3.1 Audio alarm

When alarm occurs, the monitor will make different sound to indicate alarms in different levels.

- High:"beep-beep-beep---beep-beep, beep-beep-beep---beep-beep", frequency: every 8 seconds
  - Medium: "beep--beep-beep", frequency: every 8 seconds
  - Low: "beep", frequency: every 8 seconds
- Sound pressure range: 45 dB~85 dB

#### 5.3.2 Light alarm

When alarm occurs, the alarm indicator will prompt different levels of alarms with different colors and flicker frequencies..

- High: alarm indicator flickers in red with high frequency
- Medium: alarm indicator flickers in yellow with low frequency
- Low: alarm indicator lights in yellow without flickering

#### 5.3.3 Alarm message

When alarm occurs, alarm messages will be displayed in physiological alarm area and technical alarm area. For physiological alarms, the following marks will be used in front of the messages to indicate the alarm level.

- High: \*\*\*
- Medium: \*\*

- Low: \*

The system also adopts different background to indicate the alarm level of physiological alarm and technical alarm.

- High: red
- Medium: yellow
- Low: yellow

**NOTE:**

- If one monitoring system has multiple alarm equipment, when an alarm occurs, the visual and audio prompts generated by all alarm equipment should keep the same.
- The way of alarm prompting is related to its level.
- When alarms of different levels occur at the same time, the monitor prompts the highest level alarm among them.

#### 5.4 Alarm setup

Select "ALARM SETUP" item in the "SYSTEM SETUP" menu, the initial password is "70808". Under this interface, user could set information about alarm sound and so on.

- ALARM VOL: selective from 1~7, 1 is the minimum volume, 7 is the maximum volume.
- ALM REC TIME: three options: 8 s, 16 s, 32 s.
- ALM PAUSE TIME: two options: 1 min and 2 min.
- ALM TYPE: UNLATCH.. "UNLATCH" refers to the situation that once the causes of alarm are eliminated, the alarm will disappear automatically.
- KEYVOL: selective from 1~7 and OFF.
- ALM SOUND: it can be set as "OFF", and the symbol "" will appear on

the screen.

The system will cancel the "OFF" of alarm sound in the following situations:

- ◆ The monitor is restarted;
- ◆ The alarm status is changed, for example, the system enters alarm pause status, or the alarm sound is forbidden.

---

#### WARNING

- Before starting monitoring, please check whether the settings of alarm limit are suitable for patient.
  - Invalid alarm system may occur when setting the alarm limit to the limit value.
  - When the alarm sound is turned off, the monitor will not make any sound even if a new alarm is triggered. Therefore, user must carefully choose whether to turn off the alarm sound.
  - In SILENCE or ALARM PAUSE status, set the alarm sound is as "OFF", then the system will automatically terminate the status of SILENCE or ALARM PAUSE.
  - When the alarm sound is "OFF", if the operator selects "SILENCE" or "ALARM PAUSE", the alarm sound will be restored to the previous volume when it is turned off, and at this time, the system will enter the status of silence or pause accordingly.
  - Do not rely on the sound alarm system only for patient monitoring, user should pay close attention to the patient's actual clinical situation.
- 

#### NOTE:

- When alarm sound is turned off, a symbol "" will be displayed in technical alarm area.
- The alarm sound off is only valid when the device keeps turning on, once the

device is restarted, this setup to will be restored to the previous set value.

- The symbol "" means that the alarm sound is turned off, the system could not make any sound for the alarm, so user must be careful when using this function. There are two ways to exit this status. Method 1: Set the alarm sound as "ON" in the "ALARM SETUP". Method 2: Press the "SILENCE" button, the symbol will become "", then press the "SILENCE" button one more time, the system will return to normal alarm status.
- Parameter alarm setup
  1. The parameter alarms can be set in "PARAM ALM SETUP", or their individual parameter menu.
  2. When a parameter alarm is off, a symbol "" displays near the parameter.
  3. For the parameter whose alarm is set to "ON", the alarm will be triggered when at least one of the parameters exceeds alarm limit. The monitor will take the following actions:
    - ◆ The screen displays the alarm information in a mode as described above;
    - ◆ The monitor beeps in its corresponding alarm level and volume;
    - ◆ Alarm indicator lights or flickers;
    - ◆ Information of all parameter values at the alarm moment, and the waveform 4/8/16 seconds before and after the alarm are stored.
    - ◆ If alarm recording is on, the recorder starts alarm recording. Refer to

the chapter *Recording* for details.

- ◆ The following information can be set in parameter alarm setup.
- ◆ ECG ALM SETUP: HR alarm, alarm level, alarm limits (high/low), ST alarm setup, ARR alarm setup;
- ◆ SpO<sub>2</sub> ALM SETUP: SpO<sub>2</sub> ON/OFF, alarm level, SpO<sub>2</sub> alarm limits (high/low), PR on/off, PR alarm limits (high/low);
- ◆ NIBP ALM SETUP: ON/OFF, alarm level, SYS alarm limits (high/low), MAP alarm limits (high/low), DIA alarm limits (high/low);
- ◆ RESP ALM SETUP: ON/OFF, alarm level, alarm limits (high/low), apnea alarm;
- ◆ TEMP ALM SETUP: ON/OFF, alarm level, T1 alarm limits (high/low), T2 alarm limits (high/low), TD alarm limits (high).
- ◆ IBP ALM SETUP: alarm switch, alarm level, upper and lower alarm limit of current label name.
- ◆ CO<sub>2</sub> ALM SETUP: alarm switch, alarm level, upper/lower limit of CO<sub>2</sub> alarm, upper limit of INS alarm, upper/lower limit of AWRR alarm, apnea alarm.

## 5.5 Alarm status

Except general alarm conditions, you can set the monitor to four different alarm status as below according to your need. The four alarm status have different symbols:



Alarm pause



Alarm off



Silence



Alarm sound off

### 5.5.1 Silence

Keep pressing the "SILENCE" button (over 1 second) on the control panel will turn off all the sounds. In SILENCE status, pressing the "SILENCE" button (no more than 1 second) will switch to the "ALARM PAUSE" status, and the alarm will be suspended temporarily in accordance with the time set before. In SILENCE status, keep pressing the "SILENCE" button (over 1 second), the system will exit current status and restore the alarm sound correspondingly, and back to normal alarm status. When the system is in "SILENCE" state, any new triggered alarm can terminate the "SILENCE" state, the system will return to normal alarm state (sound and light alarm).

### 5.5.2 Alarm pause

Press "SILENCE" button on the control panel to turn off all alarm sound, light prompt and physiological alarm information, so that the system will enter the "ALARM PAUSE" state. The countdown of alarm pause is displayed in the

physiological alarm area and the symbol "" is displayed in this area as well.

Time period of Alarm Pause: 1 min and 2 min. When the "SILENCE" button is pressed again, the system will restore to its normal state. In addition, a new triggered alarm can also eliminate the "ALARM PAUSE" state, and the

symbol "" disappears.

**NOTE:**

- After returning to the normal state, the presence of an alarm depends on whether the alarm condition is appropriate, but after the "SILENCE" button is pressed, the system will permanently turn off the alarm sound for lead-off or probe-off.
- The alarm pause time can be set in the "ALARM SETUP" menu as required, the default setting is 2 min.

## 5.6 Measures for Alarm occurs

The alarm message appears in system information area or system alarm area. It is needed to identify the alarm and take actions appropriately according to the cause of the alarm.

1. Check the patient's condition;
2. Confirm the alarming parameter or the type of the alarm;
3. Identify the cause of the alarm;
4. Silence the alarm, if necessary;
5. When cause of alarm has been solved, check alarm is working properly.

You will find the alarm messages and prompts for each parameter in corresponding chapters related to this parameter in this manual.

## 5.7 Probe-off alarm

If the system alarms for probe falling off, user can press the "SILENCE" button on the front panel of the monitor. At this time, the alarm indicator stops flicking and the monitor enters the ALARM PAUSE state. Press the "SILENCE" button again or wait until the alarm pause is over, the monitor will no longer generate sound alarm for probe falling off, and instead remind the user in the form of alarm messages.

## Chapter 6 Freeze

When monitoring a patient, you may freeze the waveform to view it carefully. Up to 34 seconds waveform can be reviewed. Besides, the frozen waveform can be output by recorder. The Freeze function of this monitor has following features:

- Freeze status can be activated under any operating screen.
- When entering the Freeze status, the system exits all other operating menus. At the same time, the system freezes all waveforms in the Waveform area, or full-lead ECG waveforms and the extra waveform (if available) on the Full-lead ECG screen. Nevertheless the Parameter area refreshes normally.
- The frozen waveforms can be reviewed or recorded.

### 6.1 Enter/Exit Freeze Status

#### 6.1.1 Enter Freeze Status

In the Non-Freeze status, press the "FREEZE" button on the front panel of the monitor to let the system exit the Menu being currently displayed (if available), then enter the Freeze status and display the popup "FREEZE" menu. In the Freeze status, all waveforms are frozen. In other words, the system will no longer refresh the waveforms.

#### 6.1.2 Exit Freeze Status

In the Freeze status, executing any of the following operations will command the system to exit the Freeze status:

- Select the "EXIT" option on the "FREEZE" menu;
- Press the "FREEZE" button on the front panel again;
- Press the non-immediate-to-execute button on the front panel and system buttons of MAIN and MENU;

- Execute any operation that may trigger the adjustment of the screen or display of a new menu.

After exiting the Freeze status, the system will discharge the Freeze status, clear screen waveforms and resume to display real-time waveforms.

## 6.2 FREEZE Menu

Press the "FREEZE" button on the panel, the FREEZE menu will appear on the bottom part of the screen. At the same time, the system enters the Freeze status.

- WAVE 1: to select the first frozen waveform to record. The pull-down list of this item gives you the names of all frozen waveforms displayed on the screen.
- WAVE 2: to select the second frozen waveform to record. The pull-down list of this item gives you the names of all waveforms displayed on the screen.
- RECALL: to review frozen waveforms.
- REC: after selected, the system begins recording the frozen waveforms selected in "WAVE 1" and "WAVE 2".
- EXIT: after pressed, the system closes the FREEZE menu and exits the Freeze status.

## 6.3 Reviewing Frozen Waveform

By moving the waveform, you may review a waveform of 34 seconds before the moment when it is frozen. For a waveform less than 34 seconds, the remaining part is displayed as a straight line. Use the rotary knob to move the cursor to the "RECALL" option on the FREEZE menu. Press the knob, the option displays "L-RIGHT". By turning the knob left or right, the frozen waveform on the screen will move left or right correspondingly. There is an arrow indicating upward under the right side of the last waveform. There is also a time scale beside the arrow. "0

s" is used to mark the moment when waveforms are frozen. With waveforms moving right, this time mark will turn into "-1 s, -2 s, -3 s...".

#### 6.4 Recording Frozen Waveform

In the Freeze status, you may output displayed frozen waveforms via the recorder. Maximum 2 waveforms can be output at one time. On the FREEZE menu, the pull-down lists of both "WAVE 1" and "WAVE 2" give you all names of frozen waveforms on the screen, from which you may select two waveforms. Select the "REC" option on the FREEZE menu to output parameters generated upon the freezing moment and the two selected frozen waveforms. If one of the two selected waveforms is set off or not available, only parameters and the other waveform are recorded. If these two selected waveforms are all set off or not available, only parameters are recorded. As for the function of recording frozen waveforms, you can only record the waveforms displayed upon the freezing moment. The recording time length is the same as the length of the waveform displayed on the screen. For example, if the speed of a waveform is relatively fast, then it needs shorter time to record it. When recording frozen waveforms, the system is still in the Freeze status. After completion of this recording, if required, you may select another waveform to be output, and select "REC" option again to record until the all necessary waveforms are recorded. You may also record frozen waveforms by pressing the "REC/STOP" button on the front panel. If selecting "REC" option without installing a recorder, the system will prompt "RECORDER ERROR" in the status bar. For more detailed information about recording, please refer to the chapter *Recording*.

## Chapter 7 Recording

### NOTE:

- The recorder is an optional component.

### 7.1 General Information for Recorder

A thermal array recorder is used for the Monitor.

#### Performance of the Recorder

- Recording speed: 25 mm/s or 50 mm/s.
- Waveform recording width: 48mm
- It can record up to 2 waveforms.
- The time and waveform of real-time recording are user-configurable.
- Auto recording interval is set by user, the waveform is in accordance with the real time recording.
- Allarm recording waveform is automatically selected by the monitor.

### NOTE:

- It is recommended to stop the recording when low battery alarm generated. Otherwise, the device may shutdown for out of power.

### 7.2 Recording Type

The monitor provides several stripe recording types:

- Continuous real-time recording
- 8 seconds real-time recording
- Auto 8 seconds recording
- Alarm recording
- Freeze waveform recording
- Trend graph/table recording
- ARR review recording

- Alarm recall recording
- NIBP recall recording
- SD recall recording
- Drug calculation titration recording

### **Real-time Recording**

Real-time recording starts as you pressing the "REC/STOP" button on the recorder.

The waveforms for continuous real-time recording and continuous 8 seconds recording are set in system setup (usually the first two waveforms are displayed on the screen). You can also configure it through the menu. Refer to related section for details. In RECORD SETUP menu, user can choose to print two different waveforms at the same time, or print only one waveform by setting the other waveform off. If two waveforms are set off, the real time record will print out measured parameters only.

#### **NOTE:**

- If certain recording is in process, and another parameter demands alarm recording, it will only be executed after the earlier recording is finished.

### **Auto Recording**

The monitor starts a recording for 8 seconds according to interval time set in the "TIMING REC TIME" of the "RECORD SETUP " menu. Refer to the section "RECORD" in system setup for details.

### **Alarm Recording**

- Parameter Alarm

The monitor records waveforms 4/8/16 seconds before and after the alarm (totally 8, 16 or 32 seconds) (which can be selected in System Menu).

All parameter values during the alarm will also be recorded.

Two waveforms will be output according to the following rules:

- 1) If multiple parameter alarms are switched on and triggered simultaneously, the recorder will print out those of the highest level. If parameters have same alarm level, latest alarm will be printed out.
- 2) If an alarm occurs during the recording of another parameter, it will be printed out after the current recording is finished.
- 3) If many alarms occur at the same time, their waveforms will be stored, and then printed in turn.

- ST Segment Alarm

The monitor records 2-channel ECG waveforms 4, 8, or 16 seconds prior to and after the ST alarm (totally 8, 16, or 32 seconds) (which can be selected in the menu). All parameter values during the alarm will also be recorded.

- Arrhythmia Alarm

The monitor records the waveform 4 seconds prior to and after the alarm (totally 8 seconds). All measurement results during the alarm will also be recorded.

### **Freeze Waveform Recording**

The monitor prints out the selected waveforms under the FREEZE mode. In this way you can capture the abnormal waveforms on the screen by freezing and record it.

### **Trend Graph/Table Recording**

Monitor can print out trend graph and table in current trend review interface.

### **Arrhythmia Review Recording**

Monitor can print out arrhythmia alarm event in current ARR RECALL interface.

### **Alarm Recall Recording**

Monitor can print out the alarm events in the current ALARM RECALL interface.

### **NIBP Recall Recording**

The monitor can print out all the NIBP review events in NIBP RECALL interface.

## **SD Recall Recording**

The monitor can print out the trend data of the case currently review.

## **Titration Table**

The monitor can print out the messages in the current TITRATION interface.

## **Notes on Recording**

- Recording type:
  - Real-time recording
  - Periodic recording
  - Para alarm recording
  - Arrhythmia recording
  - Freeze waveform recording
  - Trend Graph
  - Trend Table
  - Para alarm review
  - NIBP review
  - Titration Table
- Alarm parameters, alarm time and freeze time
- Patient bed number, sex, height, weight, date of birth, admission date
- Parameter name and value
- Recording time
- Waveform name
- Waveform amplitude (for ECG waveform only)
- ECG lead, scale, filter mode (if having ECG waveforms, it will be printed out within the first second or when changing the lead, gain and filter mode during real-time recording.)
- Date and time

### 7.3 Recording Start&Stop

Here are the methods for how to start the recording of each type:

Continuous real-time recording	Press REC/STOP to start/stop the recording.
8 seconds real-time recording	Press REC/STOP to start recording. It will automatically stop after 8 seconds recording.
Auto recording	The monitor starts a recording according to interval time set in the "TIMING REC TIME" of the "RECORD" menu. It will automatically stop after 8 seconds recording.
Alarm recording	When alarm recording is set ON, it automatically starts a recording when alarm occurs.
Frozen waveform recording	After accessing FREEZE menu, use knob to select two waveforms to be output. Then press REC button in the menu to print out the waveforms. If both "WAVE 1" and "WAVE 2" are set to "OFF", the measured parameters in frozen are printed out only.
Trend graph recording	Select "REC" button in the "TREND GRAPH" menu to print out the currently displayed trend graph.
Trend table recording	Pick "REC" button in the "TREND TABLE" menu to printout the currently displayed trend table.
Arrhythmia review recording	Select "REC" button in the "ARR RECALL" menu to print out the currently displayed arrhythmia waveform and related parameters.
Alarm review recording	Access the "ALARM RECALL" interface from "SYSTEM MENU", select "REC" button to print out the waveform and related parameters currently displayed.

NIBP review recording	Access the "NIBP RECALL" interface from "SYSTEM MENU", select "REC" button to print out the NIBP values currently displayed.
Titration table recording	Access the "TITRATION" interface from "DRUG CALC" menu, select the "REC" button to print out the titration information currently displayed.

Access the "RECORD" menu from the "SYSTEM SETUP" menu. Then select the "CLEAR REC TASK" button, all recording tasks will be stopped, and all stored alarms will be cleared.

#### NOTE:

- You can press REC/STOP button on the control panel to stop any current recording process.

### 7.4 Recorder Operations and Status Messages

#### Requirement for Record Paper

Only record paper satisfied the requirement can be used, otherwise the recorder may not work normally, or the recording quality may be poor, or the thermosensitive printer head may be damaged.

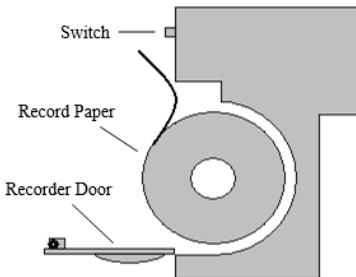
#### Proper Functioning

- When the recorder is working, the record paper goes out steadily. Do not pull the paper, or the recorder will be damaged.
- Do not operate the recorder without record paper.

#### Paper Out

When "RECORDER OUT OF PAPER" alarm is displayed, the recorder cannot start. Please insert record paper properly.

## Inserting Paper



- Press the switch to open the recorder door.
- Insert a new roll of paper into the paper cassette, put the paper correctly and pay attention to the edges.
- Give out the paper from the recorder outlet.
- Close the recorder door.

### NOTE:

- Be careful when inserting paper. Avoid damaging the thermosensitive printer head. Unless replacing the recorder paper or troubleshooting, do not leave the recorder door open.

## Removing Paper Jam

When the recorder functions or sounds improperly, open the recorder door to check whether paper jam exists. If yes, re-install the recorder paper.

## Recorder Status Message (Technical Alarm)

Message	Cause	Alarm Level	Solution
RECORDER OUT OF PAPER	Record paper runs out.	Low	Insert a new roll of record paper.
RECORDER ERROR	The communication of recorder is abnormal.	Low	Tun off the monitor and restart it.

After restarting monitor, if error still exists, contact our service engineers please.

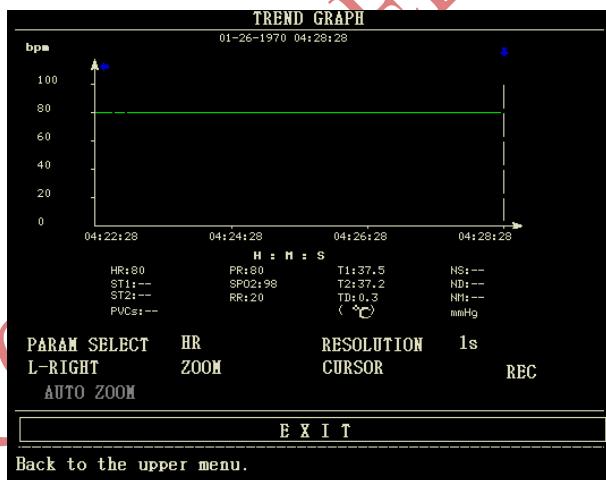
## Chapter 8 Recall

The monitor provides 480-hour trend data of all parameters, storage of 4800 groups of NIBP measurement results and 72 alarm events. All these data can be output through recorder. By using SD card, the trend data and 72-hour ECG waveform can be reviewed. This chapter gives detailed instruction for reviewing these data.

### 8.1 Trend Graph

- The latest 1-hour trend is displayed in a resolution of every 1 or 5 seconds;
- The latest 480-hour trend is displayed in a resolution of every 1, 5 or 10 minutes;

Pick "TREND GRAPH" in the SYSTEM MENU to call up the following menu:



The y-axis stands for measured value and x-axis stands for time. The symbol "" in above figure is the cursor of trend graph. The value that the cursor points to, is displayed under the trend graph, and its corresponding time is displayed above

" in above figure is the cursor of trend graph. The value that the cursor points to, is displayed under the trend graph, and its corresponding time is displayed above

the trend. Other trends except NIBP trend are displayed in continuous curves. In NIBP trend graph, the symbol "\*" represents the coordinate of the NIBP value.

#### **To select trend graph of a specific parameter:**

Pick PARAM SELECT item by using the cursor, and select a requested parameter name by turning the knob, then the trend graph of this parameter will be displayed.

#### **To select 1-hour or 480-hour trend graph:**

Pick RESOLUTION item by using the cursor, choose 1 s/5 s for 1-hour trend graph and 1min/5 min/10 min for 480-hour trend graph.

#### **To view earlier or later trend curves:**

When "➡" appears on the right part of the screen, pick "L-RIGHT" button, turn the knob clockwise to view later trend curves. When "⬅" appears on the left part of the screen, select the "L-RIGHT" button, turn the knob counterclockwise to view earlier trend curve.

#### **To change the display scale**

Pick the "ZOOM" button to adjust the y-axis scale and thus change the trend curve in proportion. The value beyond maximum value will be represented by the maximum value.

#### **To obtain trend data of a specific time**

Select "CURSOR" button, and turn the knob to left/right, then the cursor will move accordingly, and the time to which the cursor points will change too.

Parameter at this time is displayed below the x-axis. When "➡" appears on the right part of the screen, the trend graph pages down for later trend curve as the cursor moves here. When "⬅" appears on the left part of the screen, the trend graph pages up for earlier trend curve as the cursor moves here.

## To print out the trend curve

Press REC button to print out the trend curve of current selected parameter through the recorder.

## Auto Zoom

The AUTO ZOOM is available only when the PARAM SELECT is set as "NIBP". If the current measured value exceeds the scale range, click "ATUO ZOOM" button, the scale will automatically adjust to proper range for current measurement.

## Event marks on the trend graph

If an event is marked A, B, C, or D, then on the trend graph, the event type (A, B, C, or D) will be displayed at the point corresponding to the moment of marking.

## Operation example

To view the NIBP trend graph of the lastest 1 hour:

- Select the "MENU" button on the front panel, the "SYSTEM MENU" will pop up.
- Pick TREND GRAPH item.
- Select the "PARAM SELECT" item, switch to "NIBP" by turning the knob.
- Adjust the "RESOLUTION" to 1s or 5 s.
- Select the "L-RIGHT" button, turn the knob to view the changes of trend graph time and trend curve.
- Stop at requested trend time section for careful review. Pick the ZOOM button to adjust the display scale if necessary.
- For measurement result of a specific time, pick CURSOR to move the cursor to this point, corresponding time and value will be displayed above and below the curve respectively.

- For printout of trend graph, pick REC to print the NIBP trend currently displayed.
- Pick EXIT to finish the reviewing.

## 8.2 Trend Table

- The latest 480-trend table data can be displayed at every 1 min, 5 min, 10 min, 30 min, or 60 min.

Pick TREND TABLE in the SYSTEM MENU to call up the following menu:

TREND TABLE				
TIME	EVENT	HR (bpm)	PVCs (/min)	>
(26)04:28		80	--	
(26)04:27		80	--	
(26)04:26		80	--	
(26)04:25		80	--	
(26)04:24		80	--	
(26)04:23		80	--	
(26)04:22		80	--	
(26)04:21		80	--	
(26)04:20		80	--	
(26)04:19		80	--	
(26)04:18		80	--	
(26)04:17		80	--	
RESOLUTION: 1min UP/DOWN L-RIGHT REC REC ALL				
E X I T				
Back to the upper menu.				

Time corresponding to each group of trend data is displayed at the leftmost list with date in brackets. Marked events are listed under the "EVENT" corresponding to the time of marking. Trend data of all parameter is divided into 6 groups.

HR , PVCs

ST1, ST2

RR

T1, T2, TD

SpO<sub>2</sub>, PR

NIBP (S/M/D)

### To select trend table of a specific resolution:

Select the "RESOLUTION" item by using the cursor, turn the knob to change the options under resolution, then the time interval of trend data will be changed.

### To view earlier or later trend data:

When a "up arrow" appears on the upper part of the screen, pick "UP/DOWN" button, turn the knob clockwise to view later trend data. When a "down arrow" appears on the upper part of the screen, select the same item, turn the knob counterclockwise to view earlier trend data.

### To view trend data of different parameter

Pick L-RIGHT to select one from the 6 groups of parameters. A ">" by the rightmost item indicates following page available. And "<" by the leftmost item indicates previous page available.

### To print out the trend table

Press REC button to print out the trend data of all parameters currently displayed through the recorder.

### Event marks on the trend data

If an event is marked A, B, C, or D, the event type (A, B, C, or D) will be displayed at corresponding time in the trend table.

### Operation example

To view the NIBP trend table:

- Select "MENU" button on the front panel, the "SYSTEM MENU" will pop up.
- Pick TREND TABLE item.
- Select the "L-RIGHT" item, switch to "NIBP" by turning the knob.
- Adjust the "RESOLUTION" to the option that you need.

- Select the "UP/DOWN" button, turn the knob to view the NIBP trend data at different time.
- If you need to print the NIBP trend table, pick REC button, the recorder will print the NIBP trend data.
- If you need to print all trend tables, select "REC ALL" button, the recorder will print all trend data of all parameters.
- Pick EXIT to finish the reviewing.

### 8.3 NIBP recall

The monitor can review the latest 4800 groups of NIBP measurement data.

Pick NIBP RECALL in the SYSTEM MENU to invoke the result and time of the latest 9 measurements. Data is listed chronologically from the latest to the earliest. Nine measurements can be displayed in one screen. Pick UP/DOWN to view the earlier or later data. Pick REC to print out all measurement data of NIBP RECALL.

### 8.4 Alarm recall

The alarm recall includes physiological alarm recall and technical alarm recall.

- Physiological alarm recall

Select "ALARM RECALL" in the SYSTEM MENU, then select "PHYSIOLOGICAL ALM RECALL" item. In this menu, user may set the conditions for alarm review, including:

- 1) Start and End time of review

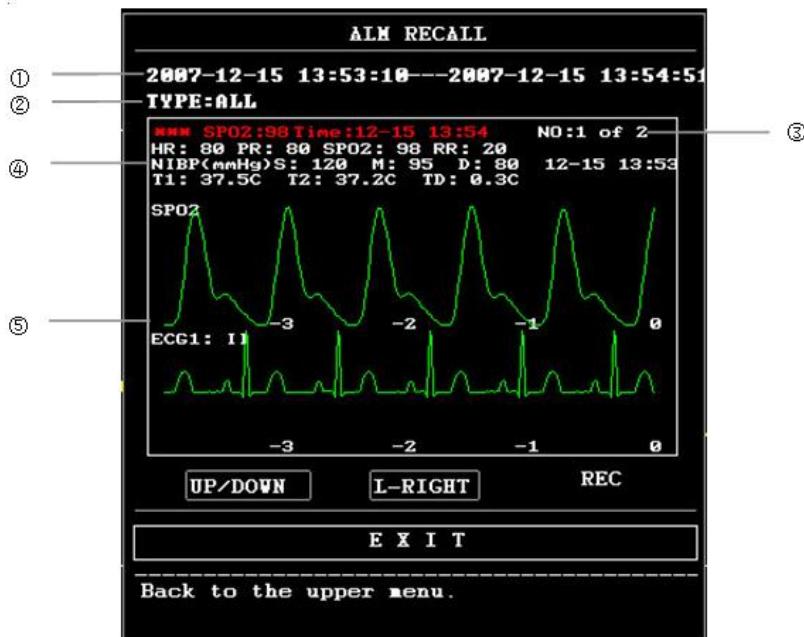
User may select the start time of review in the "BEGIN TIME" item, and the end time in the "END TIME". The end time can be set as the current time or the user-defined time.

## 2) Alarm recall event

In the pull-down list of ALARM RECALL EVENT, user can select the parameter that need to be reviewed. The selections include ALL (alarm events of all parameters), ECG, RESP, SpO<sub>2</sub>, NIBP, TEMP.

After finishing the setup of all review conditions, press the "ALARM RECALL" button to access "ALARM RECALL" menu.

The PHYSIOLOGICAL ALARM RECALL interface is shown as below:



- ① Time span (Format: year/month/day/hour/minute---year/month/day/hour/minute).
- ② Event type.
- ③ Serial number (Format: NO. xx of XX ).

- ④ The value at the moment of alarming. NIBP result is excluded.
- ⑤ Two channels waveforms, stored for 8 s/16 s/32 s.

To view all waveforms during the alarming process

Pick L-RIGHT and turn the knob to view all 8/16/32 seconds waveforms stored.

**Recording:** Select "REC" button, all review data currently displayed will be output by recorder.

- Technical alarm recall
  - 1) Select "ALARM RECALL" in the SYSTEM MENU, then select "TECHNICAL ALM RECALL" item.
  - 2) Technical alarm events are arranged chronologically from the latest to the earliest. When the number of alarm events exceeds storage range, the latest events will be displayed. Pick UP/DOWN button, and turn the knob to view the earlier or later events.

## 8.5 SD recall

User can review patient data stored in the SD card on the monitor, or on the PC by using the sync software.

An empty SD card with at least 2G capacity is needed. The SD card mounted on the monitor could memory trend data (parameters including: HR, PVCs, ST1, SpO<sub>2</sub>, PR, RR, T1, T2, TD, NIBP) and 72-hour ECG waveform. The trend data is stored per 1 minute.

**NOTE:**

- For the review on PC by using the sync software, only ECG and SpO<sub>2</sub> related waveforms and parameter values can be reviewed. Refer to the instructions of sync software for details. This chapter only introduces the reviewing method on the monitor.
- Please first set the patient's information correctly before inserting SD card.

- If different patient's data need to be saved in one SD card, you should unmount the SD card first, and then modify patient's information. Make sure that the patient number is different.

1. Enter SD OPERATE menu:

Select "MENU"→"SYSTEM SETUP"→"SD OPERATE", then you could enter the SD OPERATE menu.

2. Insert SD card

If SD card has been inserted and works normally, the prompt "SD device was found, please mount it by the button above." appears.

**NOTE:**

- If information "SD device wasn't found, please enter SD card" appears, you should exit "SD OPERATE" menu, check if SD card or USB interface is normal. If the problem still exists, reboot the monitor.

3. Mount SD card

If the monitor has found the SD card, select "MOUNT DEVICE" item, the system will display messages to indicate whether the SD card has been mounted successfully.

**NOTE:**

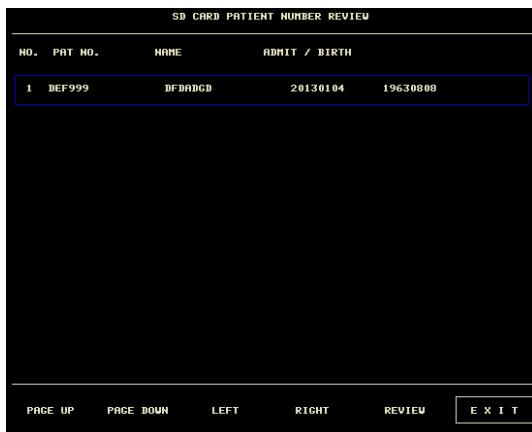
- Data can be reviewed only after SD card has been mounted successfully for 90 seconds . Otherwise the two buttons "REVIEW TREND" and "REVIEW ECGWAVE" are invalid.

4. Review trend

- Review trend

**① Select "REVIEW TREND" item in SD OPERATE menu.**

The following menu will pop up. In this menu, you can select any patient you want to review.



The items from left to right in this menu are No., patient No., patient name, admission date and birth date. The information is displayed according to the content set in patient setup. The buttons at the bottom of menu includes:

- ◆ PAGE UP/PAGE DOWN: observe patient lists of other page.
- ◆ UP/DOWN: move the cursor to select a specified patient.
- ◆ REVIEW: press this button to call up the patient trend information.

**② Reading trend data's information**

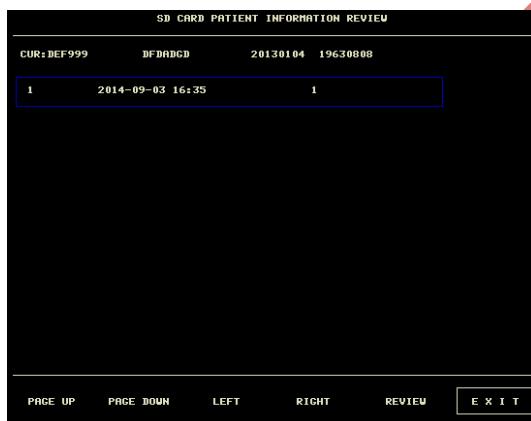
The menu displays the trend data's information according to the selected patient. The header, from left to right is:

- ◆ Patient No.
- ◆ Patient's name
- ◆ Admission date

- ◆ Birth date

The content of list, from left to right is:

- ◆ The list number
- ◆ The time that the patient data was reviewed.
- ◆ The size of data having been saved to the time that the patient data was reviewed.



### ③ Review trend data

Select an item in above menu by using the cursor, then press "REVIEW" button, the trend data will be displayed in a list. The resolution is 1 minute.

SD CARD TREND DATA REVIEW			
PAT NO.	NAME	DATE	COUNT
DEF999	DFDADGD	2014-09-03	01/01
TIME	< HR	PVCs	>
(03)16:36	80	27	

REC INT    1MIN    REC    PAGE UP    PAGE DOWN    LEFT    RIGHT    **EXIT**

The buttons are:

- ◆ Page UP/ PAGE DOWN: to view trend data of different time.
  - ◆ LIGHT/ RIGHT: to view trend data of different parameter.
  - ◆ REC: to print current list.
- Review ECG waveform
- ① Select the "REVIEW ECG WAVE" button in SD OPERATE menu, then choose a specific patient to review.

SD CARD PATIENT NUMBER REVIEW		
NO.	PAT NO.	NAME
1	DEF999	DFDADGD

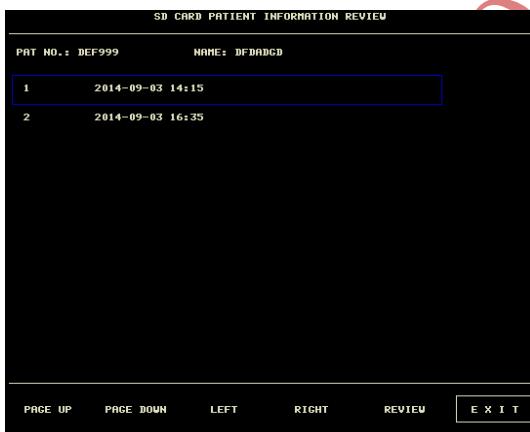
PAGE UP    PAGE DOWN    UP    DOWN    **REVIEW**    **EXIT**

## ② Select time span you want to review

ECG data is saved in many different files. It need save ECG data in a new file per half an hour. For example, "2014-09-03 14:15" represents ECG file name, it also indicates the starting time that the file is saved.

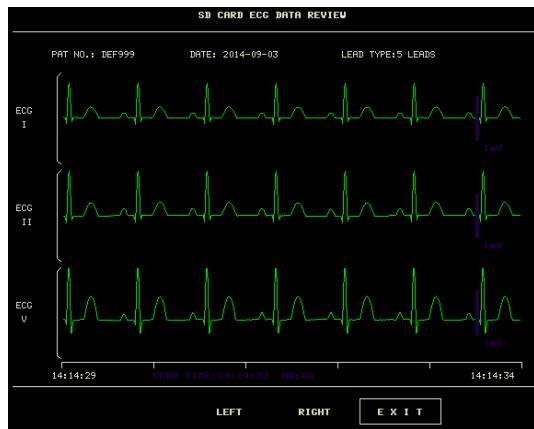
Select the time span:

- ◆ To review the ECG waveform about "2014-09-03 14:15"
- ◆ By pressing cursor, select the item "1 2014-09-03 14:15"
- ◆ Press "REVIEW" button.



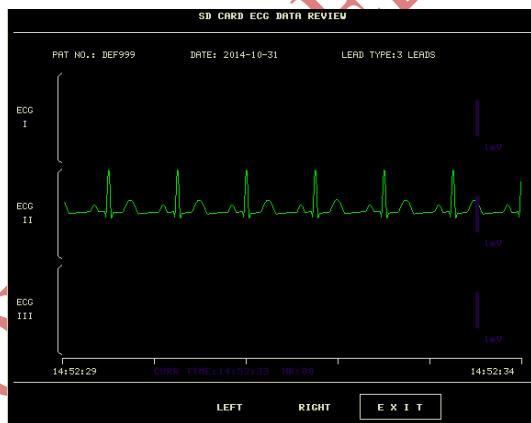
## ③ Review ECG waveform

- ◆ The time span of one window is 5s.
- ◆ The window can display 3 channels ECG waveform. When the lead type is "5 LEADS", it displays ECG I, ECG II and ECG V.



5-Lead

- ◆ When the lead type is "3 LEADS", it can displays only one channel waveform. The ECG lead is the same with the one displayed on the monitor.



## 5. Unmount SD card

Enter "SD OPERATE" menu, press "UMOUNT DEVICE". You can take out SD card only when the system displays the prompt "UMOUNT SD CARD SUCCESSFULLY, YOU CAN TAKE OUT THE CARD NOW."

## Chapter 9 Drug Calculation and Titration Table

This Portable Patient Monitor provides drug calculation and titration table display functions for fifteen drugs and outputs the content of titration table on the recorder.

### 9.1 Drug Calculation

The drug calculations that can be performed by the system are AMINOPHYLLINE, DOBUTAMINE, DOPAMINE, EPINEPHRINE, HEPARIN, ISUPREL, LIDOCAINE, NIPRIDE, NITROGLYCERIN and PITOCIN. Besides DRUG A, DRUG B, DRUG C, DRUG D and DRUG E are also provided to flexibly replace any of the drugs.

Select "DRUG CALC" in SYSTEM MENU, the following interface will appear:

DRUG CALC					
DRUG NAME	Drug A	INF RATE	---	ml/hr	
WEIGHT	154.0	lb	Drip Rate	---	GTTr/min
AMOUNT	---	mg	DROP SIZE	---	GTTr/ml
VOLUME	---	ml	DURATION	---	hr
CONCENTRAT	---	mg/ml			
DOSE/min	---	mcg			
DOSE/hr	---	mg			
DOSE/kg/min	---	mcg			
DOSE/kg/hr	---	mcg	TITRATION>>		
<hr/> EXIT <hr/>					
Back to the upper menu.					

The following formulas are applied for dose calculation:

$$\text{Concentration} = \text{Amount} / \text{Volume}$$

$$\text{INF Rate} = \text{Dose}/\text{Concentration}$$

$$\text{Duration} = \text{Amount} / \text{Dose}$$

$$\text{Dose} = \text{Rate} \times \text{Concentration}$$

#### Operating method:

In the Drug Calculation window, the operator should first select the name of the

drug to be calculated, and then confirm the patient weight. Afterwards, the operator should also enter other known values.

Turn the knob to move the cursor to each calculation item in the formula, press the knob and turn it to select a value. When the calculated value is selected, the result of other items will be displayed correspondingly. Each calculation item has a range limit, and if the result is out of range, the system will display "---".

**NOTE:**

- For the drug calculation, the prerequisite is that the operator must first of all enter the patient weight and drug name. Values given by the system at the beginning are a group of random initial values, which cannot be used as the calculation reference. Instead, a new group of values suitable for the patient should be entered according to doctor's advice.
- Each drug has its fixed unit or unit series. Operator must select the proper unit following the doctor's instruction. The unit will automatically adjust itself in its unit series according to the input value. If the result expressed by this unit exceeds the range, the system will display "---".
- After entering a value, a conspicuous prompt will appear in the menu warning the operator to confirm the correctness of the entered value. The correctness of input value is the guarantee for the reliability and safety of the calculated results.
- In neonate mode, Drip Rate and Drop Size items are disabled.
- For each entered value, the system will always give a dialog box asking for user's confirmation. You must be careful when answering each box. The calculated result is reliable only when the entered values are correct.

Select the drug name: Turn the knob to pick the DRUG NAME item. You may select the drug name in the pull-down list, including AMINOPHYLLINE,

DOBUTAMINE, DOPAMINE, EPINEPHRINE, HEPARIN, ISUPREL, LIDOCAINE, NIPRIDE, NITROGLYCERIN, PITOCIN, Drug A, Drug B, Drug C, Drug D and Drug E.

Calculation for only one type can be generated each time.

**NOTE:**

- Drug A/B/C/D/E are only codes for drugs instead of their real names. The units for these five drugs are fixed. The operator may select the appropriate units according to the convention of using these drugs. The rules for expressing the units are:

"mg" series units are fixedly used for drug A, B and C: g, mg, mcg.

"unit" series units are fixedly used for drug D: unit, k unit, m unit.

"mEq" is fixedly used for drug E.

Patient weight: After accessing the DRUG CALC window, the operator should enter the patient weight into the first or the second item. The entered weight will be used as the independent data only for the calculation of drug concentration.

**NOTE:**

- This drug calculation function acts only as a calculator. Information in this interface may not relate to the patient being currently monitored. That means the patient weight in Drug Calculation menu and the data in Patient Information menu are independent from each other. Therefore, if the Weight in Patient Information changes, the value in Drug Calculation will not be affected.

## 9.2 Titration Table

### Access titration table:

Select "DRUG NAME" item in DRUG CALC menu, confirm your selection, then select "TITRATION>>" to enter the titration table interface. The interface of titration table is as following:

TITRATION -- Drug A					
AMOUNT	400.00mg		VOLUME	250.00ml	
DOSE/min	2500.00mcg		INF RATE	93.75ml/hr	
WEIGHT	70.00kg		DRIP RATE	31.25GTT/min	
DOSE	INF RATE	DOSE	INF RATE	DOSE	INF RATE
0.00	0.00	10.00	0.38	20.00	0.75
1.00	0.04	11.00	0.41	21.00	0.79
2.00	0.08	12.00	0.45	22.00	0.83
3.00	0.11	13.00	0.49	23.00	0.86
4.00	0.15	14.00	0.53	24.00	0.90
5.00	0.19	15.00	0.56	25.00	0.94
6.00	0.23	16.00	0.60	26.00	0.98
7.00	0.26	17.00	0.64	27.00	1.01
8.00	0.30	18.00	0.68	28.00	1.05
9.00	0.34	19.00	0.71	29.00	1.09
BASIC	DOSE	STEP	1	DOSE TYPE	DOSE/min
		UP-DOWN		REC	
			E X I T		
Back to the upper menu.					

■ Method to operate the titration table:

- 1) In the TITRATION table, turn the knob to pick BASIC item. Press and turn the knob to select either INF RATE or DOSE or DRIP RATE.
- 2) Move the cursor to STEP item. Press the knob to select step. The selectable range is 1 ~ 10.
- 3) Move the cursor to DOSE TYPE item. Press the knob to select the unit.
- 4) Move the cursor to UP-DOWN item, press and turn the knob to view the data in previous or following pages.
- 5) Move the cursor to REC item. After pressing the knob, the recorder prints out the data displayed in the current titration table.
- 6) Move the cursor to EXIT item, press the knob to return to DRUG CALC menu.

## Chapter 10 ECG Monitoring

### 10.1 Introduction

The ECG monitoring produces a continuous waveform of the patient's cardiac electric activity to enable an accurate assessment of patient's current physiological state. Only proper connection of the ECG cables can ensure satisfactory measurement. The monitor displays 2-channel ECG waveforms at the same time in normal working, and provides 3/5-lead monitoring, ST segment analysis and arrhythmia analysis.

- The patient cable consists of 2 parts;
  - The cable that connects to the monitor;
  - The lead set that connects to the patient.
- For 5-lead monitoring, the ECG can derive two waveforms from two different leads. It is available to choose a specified lead to monitor from the left side of ECG waveform by using the knob.
- The monitor displays the Heart Rate (HR), ST segment and Arrhythmia analysis.
- All parameters above can be set as alarm parameters.

#### NOTE:

- In the default settings of the monitor, the ECG waveforms are the top two waveforms displayed in the waveform area.

### 10.2 Safety information

---

#### WARNING

- Do not touch the patient, table nearby, or the equipment during defibrillation.
- Use only the ECG cables and electrodes provided by our company for

monitoring.

- When connecting the cables and electrodes, please do make sure that the cables and electrodes are not in contact with any conductive part or the earth, especially all the ECG electrodes, including neutral electrodes are securely attached to the patient. Do not let them contact with any conductive part or the ground.
- Check the skin attached with ECG electrode patches for irritation everyday. If there is a sign of allergies, replace the electrodes every 24 hours or change the sites.
- Before starting the monitoring, inspect whether the lead works normally. Unplug the ECG cable from the socket, the screen will display the error message "ECG LEAD OFF" and the audible alarm will be activated.
- To achieve a successful defibrillation, it is required that all patches related to electrodes should be correctly attached.

---

NOTE:

- Please use defibrillation proof ECG cable during defibrillation.
- Interference from a non-grounded instrument near the patient and ESU interference can cause inaccuracy of the waveform.
- When a ECG device is unable to work, such as "ECG module communication stopped", "ECG module communication error" or "ECG module initialization error" appears, the monitor will stop monitoring automatically, and the prompt system alarm, which is a high-level alarm.
- For protecting environment, used electrodes must be recycled or disposed properly.

## **10.3 Monitoring Procedure**

### **10.3.1 Preparation**

1. Prepare the patient's skin prior to placing the electrodes.
  - The skin is a poor conductor of electricity, therefore preparation of the patient's skin is important to facilitate good contact between electrodes and skin.
  - Shave hair from the sites where electrode patches attach to, if necessary.
  - Wash sites thoroughly with soap and water. (Never use ether or pure alcohol, because this increases skin impedance).
  - Rub the skin briskly to increase capillary blood flow in the tissues and remove skin scurf and grease.
  - Before installing the electrodes, let the skin dry completely.
2. Attach clip or snap to electrodes prior to placement.
3. Install the electrodes on the patient. Before attaching, apply some conductive paste on the skin if the electrode does not contain conductive paste itself.
4. Connect the electrode lead to the patient cable.
5. Make sure the monitor is ready with power supply.

### **10.3.2 Choose Lead Type**

1. Select the ECG parameter area, enter the ECG setup menu.
2. Set the "LESD TYPE" to "3 LEADS" or "5 LEADS" according to the lead type you applied.

### 10.3.3 Installing ECG lead

The following description takes America standards as examples.

NOTE:

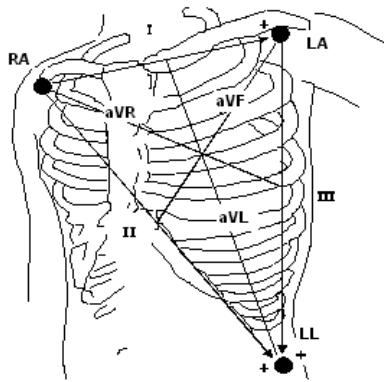
- The following table gives the corresponding lead names used in Europe and America Standards. (Lead name is represented by R, L, N, F, C and C1~C6 respectively in Europe Standard, while corresponding lead name in America Standard is RA, LA, RL, LL, V and V1~V6.)

America Stand		Europe Standard	
Lead name	Color	Lead name	Color
RA	White	R	Red
LA	Black	L	Yellow
LL	Red	F	Green
RL	Green	N	Black
V	Brown	C	White
V1	Brown/Red	C1	White/Red
V2	Brown/Yellow	C2	White/Yellow
V3	Brown/Green	C3	White/Green
V4	Brown/Blue	C4	White/Brown
V5	Brown/Orange	C5	White/Black
V6	Brown/Purple	C6	White/Purple

#### The 3-lead

The placement of 3-lead electrodes is shown as below:

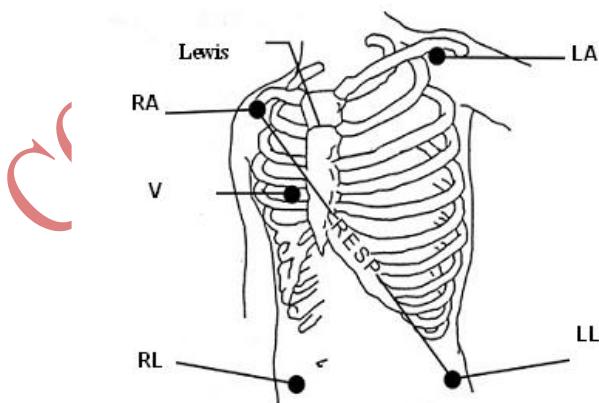
- RA (right arm): under the clavicle, near the right shoulder
- LA (left arm): under the clavicle, near the left shoulder
- LL (left leg): left lower quadrant



### The 5-lead

The placement of 5-lead electrodes is shown as below:

- RA (right arm): under the clavicle, near the right shoulder
- LA (left arm): under the clavicle, near the left shoulder
- RL (right leg): right lower quadrant
- LL (left leg): left lower quadrant
- V (chest): on the chest

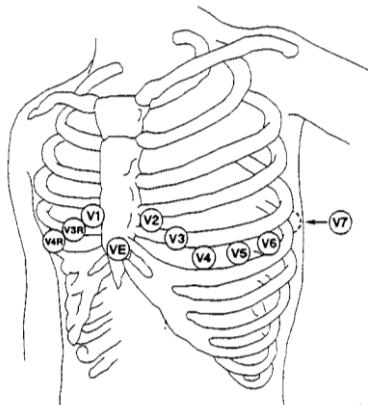


**NOTE:**

- To ensure patient safety, all leads must be attached to the patient.

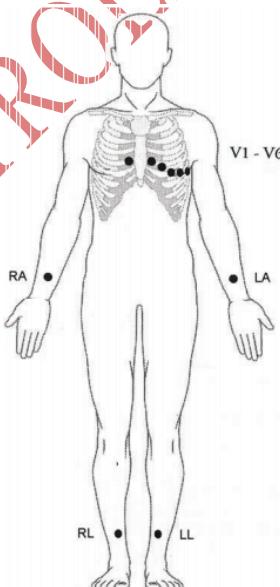
For 5-lead set, attach the chest electrode (V) to one of the indicated positions as below:

- V1: On the 4<sup>th</sup> intercostal space at the right sterna margin.
- V2: On the 4<sup>th</sup> intercostal space at the left sterna margin.
- V3: Midway between V2 and V4 electrodes.
- V4: On the 5<sup>th</sup> intercostal space at the left clavicular line.
- V5: On the left anterior axillary line, horizontal with V4 electrode.
- V6: On the left middle axillary line, horizontal with V4 electrode.
- V3R-V7R: On the right side of the chest in positions corresponding to those on the left.
- VE: Over the xiphoid position. For the placement of V-leads on the back, it should be attached on one of the following sites.
- V7 : On the 5<sup>th</sup> intercostal space at the left posterior axillary line of back.
- V7R: On the 5<sup>th</sup> intercostal space at the right posterior axillary line of back.



### The 12-lead

In American Standards, the 12-lead (10 lead cables) electrodes should be placed on limbs and chests. Limbs electrodes should be placed on the soft skin of both hands and feet, and the chest electrode should be placed according to the doctor's needs. As shown below:



## **Recommended ECG Lead Placement for Surgical Patients**

The placing of the ECG leads will depend on the type of surgery that is being performed. For example, with open chest surgery the electrodes may be placed laterally on the chest or on the back. In the operating room, artifacts can sometimes affect the ECG waveform due to the use of ES (Electrosurgery) equipment. To help reduce this you can place the electrodes on the right and left shoulders, the right and left sides near the stomach, and the chest lead on the left side of mid-chest. Avoid placing the electrodes on the upper arms, otherwise the ECG waveform will be too small.

---

### **WARNING**

- When using electrosurgery equipment, leads should be placed in a position in equal distance from electrotome and the grounding plate to avoid cautery. Electrosurgery equipment wire and ECG cable must not be tangled up.
  - When using Electrosurgery equipment, never place an electrode near the grounding of the electrosurgery device, otherwise there will be a great interference with the ECG signal.
  - When the monitor is connected to a defibrillator and other high-frequency devices, it is recommended to use anti-defibrillation ECG leads, otherwise it may cause burns to the patient.
  - When the monitor is used with a defibrillator, the operator should avoid contact with the patient or bed, and the defibrillation electrode should not touch the electrode of the monitor directly, for doing so may generate sparks then causing device damage or patient injury.
- 

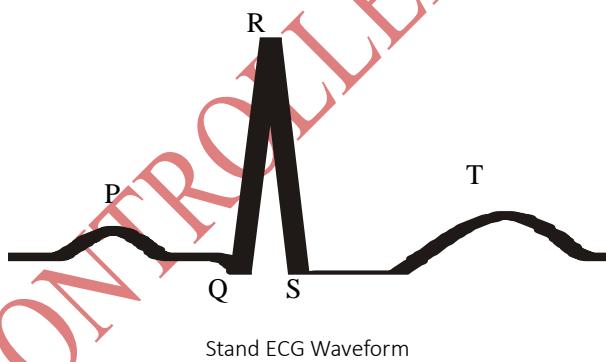
**NOTE:**

- If a ECG waveform is not accurate, while the electrodes are correctly attached, try to change the lead.
- Interference from a non-grounded instrument near the patient and ESU interference can cause inaccuracy of the waveform.

A good signal should be:

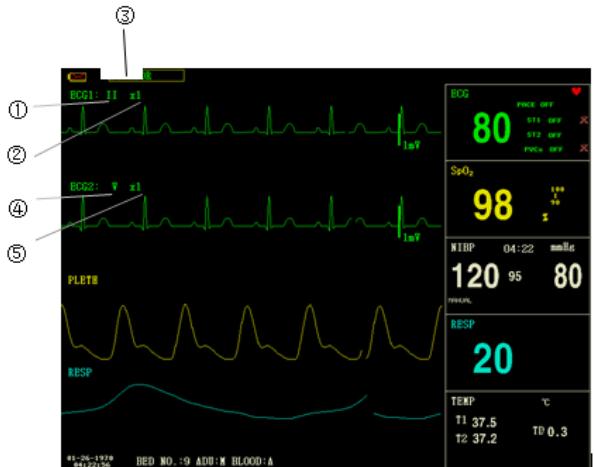
- Tall and narrow with no notches.
- With tall R-wave completely above or below the baseline.
- With pacemaker signal no higher than R-wave height.
- With T-wave less than one-third of the R-wave height.
- With P-wave much smaller than the T-wave.

To obtain a 1 mv calibrated ECG wave, the ECG should be calibrated. A message "when CAL, can't monitor!" prompts on the screen.



#### 10.4 ECG Screen Hot Keys

The following figure is an interface of 5-lead monitoring, only for reference.



ECG Hot Key

① Leads of channel 1:

- 1) The selectable leads are I, II, III, aVR, aVL, aVF, V.
- 2) When the ECG is 5-lead, the selectable leads are: I, II, III, aVR, aVL, aVF; V. When ECG is 3-lead, selectable leads are: I, II, III.
- 3) Leads on the ECG waveform must not use the same name. Otherwise, the system will automatically change the ECG waveform name that has been used to another one.

② Waveform gain of channel 1: to adjust the amplitude of ECG waveforms

Select gain value for each channel from  $\times 0.25$ ,  $\times 0.5$ ,  $\times 1$ ,  $\times 2$  and  $\times 4$ . A 1mV scale displays on each ECG channel's one side. The height of the scale is directly proportional to the waveform amplitude.

③ Filter method: to display clearer and more detailed waveform

There are three filter modes for selection. In DIAGNOSTIC mode, the ECG waveform is displayed without filter. In MONITOR mode, the artifact that may cause false alarm is filtered. And the SURGERY mode could reduce

artifacts and interferences from electrosurgery equipment. The filter mode is applicable for both channels, and it is displayed at the top of screen.

- ④ Leads of channel 2: refer to ① for detailed information.
  - ⑤ Waveform gain of channel 2: refer to ② for detailed information.
- 

#### WARNING

- Only in Diagnostic mode, the system can provide non-processed real signals. In Monitor or Surgery mode, ECG waveforms may have distortion of different extent. In either of the latter two modes, the system can only show the basic ECG, the results of ST analysis may also be greatly affected. In Surgery mode, results of ARR analysis may be somewhat affected. Therefore, it is suggested that in the environment having relative small interference, you'd better monitor a patient in Diagnostic mode.
- 

#### NOTE:

- When the input signals are too large, the peak of the waveform may not able to be displayed. In this case user could manually change the gain setup of ECG waveform according to the actual waveform so as to avoid the occurrence of the unfavorable phenomena.

#### 10.5 ECG setup

Turn the knob to move the cursor to the ECG hot key in parameter area, and press the knob to enter ECG setup menu.

- ALM REC: if set to "ON", HR alarm will be recorded once alarm happens.
- HR FROM

**ECG:** Heart rate will be detected by ECG wave.

**SpO<sub>2</sub>:** Heart rate will be detected through PLETH, the monitor prompts "PULSE"

at the right side of ECG hot key with pulse sound. Only pulse alarm is available. When the HR FROM is set to "PLETH", the system only carry on the alarm judgement of pulse rate, while the heart rate alarm will not be judged.

**AUTO:** The monitor distinguishes heart rate source according to the quality of signal. ECG source priority is higher than SpO<sub>2</sub> source. Only when the ECG signal is poor, which can not be analyzed, the system will choose SpO<sub>2</sub> source, and when the ECG signal quality returns to normal, the heart rate source automatically switch to the ECG. As long as the presence of ECG module, the heart rate value will be displayed, only when the ECG module does not exist, the pulse rate value will be displayed.

**BOTH:** The monitor displays HR and PR simultaneously. The PR value is displayed at the right side of SpO<sub>2</sub> hot key. Both HR alarm and PR alarm are available. As for the sound of HR or PR in BOTH mode, HR is given the priority, i.e., if HR is available, the system prompts the sound of heart rate, but if HR is not available, then it will prompt the sound of pulse rate.

- SWEEP

Available options for ECG SWEEP are 12.5 mm/s, 25.0 mm/s, and 50.0 mm/s.

- LEAD TYPE: to select either 5 LEADS or 3 LEADS.

- HR CHANNEL

"CH1": to count the heart rate by channel-1 waveform

"CH2": to count the heart rate by channel-2 waveform

"AUTO": the monitor selects a channel automatically for HR calculation

- ECG ALM SETUP

Input the initial password "70808" for alarm setup to enter its interface, the following items can be set:

- ◆ HR ALM: pick "ON" to enable alarm prompt and data record during the heart rate alarm; pick "OFF" to disable the alarm function,

and there will be a  in parameter area.

- ◆ ALM LEV: selectable from "HI" and "MED". Level HIGH represents the most serious alarm.
- ◆ ALM HI: to set the upper limit of HR alarm.
- ◆ ALM LO: to set the lower limit of HR alarm.
- ◆ ST ALM SETUP: refer to the section *ST Segment Monitoring* in the following for details.
- ◆ ARR ALM SETUP: refer to the section *ARR Monitoring* in the following for details.

#### NOTE:

- ECG alarm is activated when the heart rate exceeds ALM HI value or falls below ALM LO value.
- Please set the alarm limits according to clinical condition of individual patient.
- The setup of HR alarm limits is very important in monitoring process. The upper limit should not too high. Considering the factors of variability, the upper limit of HR alarm should 20 beats/min higher than the patient's heart rate at most.
  - DEF POINT: refer to the section *ST Segment Monitoring* in the following for details.
  - ARR RECALL: refer to the section *ARR Monitoring* in the following for details.
  - OTHER SET: Pick this item to access ECG SETUP menu.

- BEAT VOL: 8 selections are available: OFF, 1~7. 7 indicates maximum volume. OFF indicates no sound.
  - PACE: "ON" means the detected signal will be marked by a "1" above the ECG waveform. "OFF" means no pacemaker analysis.
- 

#### WARNING

- For a patient using pacemaker, the heart rate meter may count the pacemaker pulse when patient appears cardiac arrest or arrhythmia. Therefore, do not entirely rely on the alarms of heart rate meter. Patient with pacemaker should be closely monitored.
  - If monitoring a patient with pacemaker, set "PACE" to On. If monitoring a patient without pacemaker, set "PACE" to Off. If "PACE" is on, the system will not perform some types of ARR analysis. For detailed information, please refer to the section about arrhythmia analysis.
  - When the "PACCE" is on, the arrhythmia events related to ventricular premature beat (including PVCs count) will not be detected, neither the ST segment analysis.
- 

- NOTCH: ON/OFF.
- EMG: ON/OFF.
- PITCH TONE: ON/OFF
- ECG CAL: pick this item to start calibrating ECG. The method to end calibrating: re-select this button in the menu or change the lead name on the screen.
- ADJUST WAVE POS:
  1. CHANNEL: CHANNEL I/CHANNEL II
  2. UP-DOWN: to adjust the up and down of channel-1/channel-2 ECG waveform

3. DEF POS: return to the original position
- DEFAULT: pick this item to access the ECG DEFAULT CONFIG dialog box, in which user may select either the FACTORY DEFAULT CONFIG or the USER DEFAULT CONFIG. After selecting one item and exiting the dialog box, the system will pop up a dialog box asking for user's confirmation.

## 10.6 ECG Alarm and Prompt Message

### 10.6.1 Alarms

Alarms occurring in the process of ECG measurement contain two types: physiological alarm and technical alarm. Prompt messages may also appear in the mean time. For the audio and visual features during the appearance of these alarms and prompt messages, please refer to the related description in *Chapter 5 Alarm*. In the screen, physiological alarms and prompt messages (general alarms) are displayed in the physiological alarm area of the monitor, while technical alarms, and prompt messages that unable to trigger alarms are displayed in the technical alarm area. This section does not describe the alarm part about arrhythmia and ST analysis.

Among physiological alarms, those belonging to the type that the parameter has exceeded the limits may activate the recorder to automatically output the parameters and related measured waveforms when the alarms occur on the condition that the alarm record switch in related menu is On.

Tables below describe respectively the possible alarms those may occur during the measurement.

Physiological alarms:

Message	Cause	Alarm level
ECG SIGNAL WEAK	No ECG signal of the patient is detected.	HIGH

HR HI	Measured HR value is higher than the upper alarm limit.	User-selectable
HR LOW	Measured HR value is lower than the lower alarm limit.	User-selectable

Technical alarms:

Message	Cause	Alarm level	Solution
ECG LEAD OFF or RESP LEAD OFF	ECG electrodes fall off the skin or ECG cables fall off the monitor.	LOW	Make sure that all electrodes, leads and patient cables are properly connected.
V LEAD OFF			
LL LEAD OFF			
LA LEAD OFF			
RA LEAD OFF			
MODULE ERROR	Occasional communication failure	HIGH	If the fault persists, stop using the measurement function provided by this ECG module, and inform the biomedical engineer or maintenance personnel of our company.
NOISE	ECG measuring signal is greatly interfered.	LOW	Make sure the patient is quiet, the electrodes are properly connected and AC power system is well grounded.

## 10.7 ST Segment Monitoring

- The default setting for ST segment monitoring is "OFF", so the monitor will not process ST analysis. You can switch it to ON when necessary.
- The ST segment algorithm can measure the elevation or depression of the ST segment on the user-specified lead. The relevant ST measurement

results are displayed numerically at the parameter areas ST1 and ST2. View the trend data displayed graphically and in tables under "TREND GRAPH" and "TREND TABLE" menu.

- Unit: mV
- Measurement range: -2.0～+2.0 mV
- Meaning of the value: positive means elevating, negative means depressing.

**NOTE:**

- When setting ST ANALYSIS on, the monitor will select "DIAGNOSTIC" mode. You can set it to "MONITOR" mode or "SURGERY" mode as required. However at this time ST value has been severely distorted.

#### 10.7.1 ST ON/OFF

To set the display of ST parameter on or off:

1. Select "ECG ALM SETUP" item in the "ECG SETUP" menu, refer to the "ECG SETUP" for details;
2. Then select "ST ALM SETUP" to enter its interface, set the "ST ANALYSIS" to on or off.

#### 10.7.2 ST alarm setup

Select "ECG ALM SETUP" item in the "ECG SETUP" menu, input the initial password of alarm setup "70808", click "ST ALM SETUP" to modify the following items:

- ST ANAL: the switch for ST analysis. Set it to ON to activate the ST analysis or OFF to disable the ST analysis.
- ST ALM: pick "ON" to enable prompt message and data record during the ST analysis alarm; pick "OFF" to disable the alarm function, and there

will be a  beside parameter area ST1. ST alarm is activated when the

result exceeds the upper limit of ST value or falls below the lower limit of ST value.

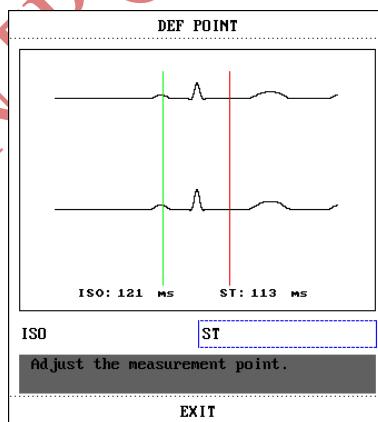
- ALM LEV: to set the ST alarm level. There are three selections: "HI", "MED" and "LO".
- ALM REC: "ON" means that the system will enable the recorder for alarm recording.
- ALM HI: to set the upper limit of ST alarm. The maximum setting is +2.0. The minimum high limit should be 0.1 larger than the set low limit.
- ALM LO: to set the lower limit of ST alarm. The minimum setting is -2.0. The maximum low limit should be 0.1 lower than the set high limit.

### 10.7.3 DEF point setup

Identify the analysis point for ST segment.

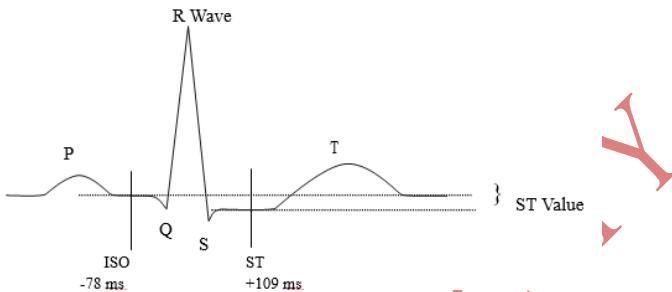
Select the "DEF POINT" item in "ECG SETUP" menu, in which the value of ISO and ST point can be set.

1. ISO (Base point): to set the baseline point.
2. ST (Starting point): to set the measurement point.



The ISO and ST are the two measurement points in ST segment, both of them can

be adjusted. The reference point is the position where the peak of R-wave locates (as figure below). The ST measurement value for each heartbeat complex wave is the difference between the two measurement points.



The position of measurement points (ISO and ST) should be adjusted at the beginning of monitoring, or the patient's HR or ECG waveform changes significantly. Abnormal QRS complex is not considered in ST segment analysis.

**NOTE:**

- Abnormal QRS complex is not considered in ST segment analysis.
- The measurement points should be adjusted if the patient's HR or ECG waveform changes significantly, detailed instructions are described in the following.

#### 10.7.4 Adjust ISO/ST point

These two points can be adjusted by turning the knob.

For ST measurement points setting, enter the "DEF POINT" window. The QRS complex template displays in the window (If the channel is switched off, the system prompts "ST ANALYSIS KEY IS OFF!"). It is adjustable of the highlight lines in the window. You may select ISO or ST, then switch the knob left or right to move the line, then to decide the baseline point and the measurement point.

**NOTE:**

- The alarm limits for two ST measurements are identical. The setting of alarm limits can not be made only for one channel.

#### 10.7.5 ST alarms and Prompt messages

Among physiological alarms, those belonging to the type that the parameter has exceeded the limits may activate the recorder to automatically output the parameters and related measured waveforms when the alarms occur on the condition that the alarm record switch in related menu is On. Possible physiological alarms during ST measurement are listed as below.

Physiological alarms:

Message	Cause	Alarm Level
ST1 HI	ST measuring value of channel 1 is above the upper alarm limit.	User-selectable
ST1 LOW	ST measuring value of channel 1 is below the lower alarm limit.	User-selectable
ST2 HI	ST measuring value of channel 2 is above the upper alarm limit.	User-selectable
ST2 LOW	ST measuring value of channel 2 is below the lower alarm limit.	User-selectable

#### 10.8 ARR Monitoring

##### Arrhythmia analysis

The arrhythmia analysis is used to monitor ECG of neonate and adult patient in clinical, detect the changing of heart rate and ventricular rhythm, and also save arrhythmia events and generate alarming information. Arrhythmia analysis can monitor the patient with or without pacemaker. Qualified personnel can use arrhythmia analysis to evaluate patient's condition (such as heart rate, PVCs

frequency, rhythm and abnormal heartbeat) and decide the treatment accordingly. Besides detecting the changing of ECG, arrhythmia analysis can also monitor patients and give proper alarm for arrhythmia.

- The arrhythmia monitoring is shutoff by default. You can enable it when necessary.
- This function can call up the doctor's attention to the patient's heart rate by measuring and classifying the arrhythmia and abnormal heart beat, and triggering the alarm.
- The monitor can conduct up to 13 different arrhythmia analysis.
- The monitor can store the latest 60 alarm events (a single-channel ECG waveform 4 seconds before and after the alarm) during the arrhythmia analysis process. The operator can edit these arrhythmia events through this menu.

#### 10.8.1 ARR Analysis ON/OFF

To set the ARR analysis on or off:

1. Select "ECG ALM SETUP" item in the "ECG SETUP" menu, refer to the "ECG SETUP" for details;
2. Then select "ARR ALARM" to enter its interface, set the "ARR ANAL" to on or off.

#### 10.8.2 ARR alarm setup

Select "ECG ALM SETUP" item in the "ECG SETUP" menu, input the initial password of alarm setup "70808", click "ARR ALM SETUP" to modify the following items:

- ARR ANAL: Pick "ON" during monitoring. Default set is "OFF".
- PVCS ALM: pick "ON" to enable prompt message and data record when alarm occurs; pick "OFF" to disable the alarm function, and

there will be a  beside PVCs parameter area.

- ALM LEV: selectable from HI, MED, LO. Level HIGH represents the most serious PVCs alarm.
- ALM REC: pick "ON" to enable the recording when PVCs alarm occurs.
- ALM HI: PVCs alarm is activated when the PVCs exceeds the set ALM HI value.
- ARR RELEARN: press this button to start a learning procedure.
- ARR ALM SETUP: to set the arrhythmia alarm. In this menu, "ALM" is the alarm switch, "LEV" is alarm level, "REC" is the switch of alarm recording.

ARR ALARM				
	ALM	LEV	REC	
RSTOLE	ON	HI	OFF	ALL ALM ON
VFIB/VTAC	ON	HI	OFF	ALL ALM OFF
R ON T	ON	MED	OFF	ALL REC ON
VT>2	ON	MED	OFF	ALL REC OFF
COUPLET	ON	MED	OFF	ALL LEV HI
PVC	ON	MED	OFF	ALL LEV MED
BIGEMINY	ON	MED	OFF	ALL LEV LOW

Page Down >> E X I T

Back to the upper menu.

#### Arrhythmia Alarm Setup

Select "Page Down" to enter the interface for following setup.

ARR MORE SET 2			
	ALM	LEV	REC
TRIGEMINY	ON	MED	OFF
TACHY	ON	MED	OFF
BRADY	ON	MED	OFF
PNC	ON	MED	OFF
PNP	ON	MED	OFF
MISSED BEATS ON		MED	OFF
			ALL ALM ON
			ALL ALM OFF
			ALL REC ON
			ALL REC OFF
			ALL LEV HI
			ALL LEV MED
			ALL LEV LOW

Page Up >>      E X I T

Back to the upper menu.

### Arrhythmia Alarm Setup

You can pick ALL ALM ON to enable alarm function of all arrhythmia types and pick ALL ALM OFF to disable this function. Likewise, you can pick ALL REC ON to enable recording function for all arrhythmia types and pick ALL REC OFF to disable this function. Changing the ALM LEV can reset alarm level of all arrhythmia types.

#### 10.8.3 ARR Recall

1. Pick this item to review and edit the ARR analysis result.
2. Select "ARR RECALL" item in the "ECG SETUP" menu, the following interface will pop up.

ARR RECALL		
CURRENT TIME 04:35:51 1/2		
PVC	1970-01-26 04:35:50	
CPT	1970-01-26 04:35:25	
MIS	1970-01-26 04:35:21	
PVC	1970-01-26 04:35:19	
CPT	1970-01-26 04:35:17	
CPT	1970-01-26 04:35:07	
PVC	1970-01-26 04:34:55	
MIS	1970-01-26 04:34:34	
PVC	1970-01-26 04:34:32	
PVC	1970-01-26 04:34:26	

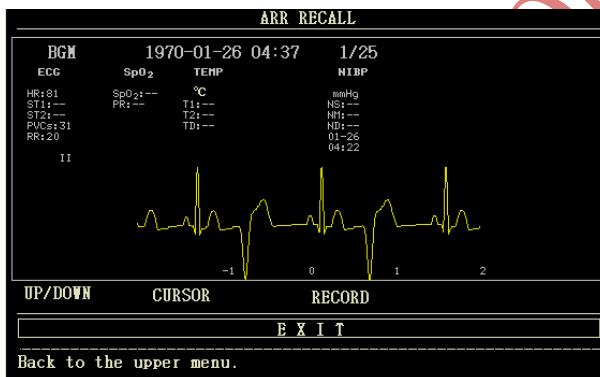
UP/DOWN      CURSOR      WAVE >>      RENAME

E X I T

Back to the upper menu.

The recent stored ARR events are listed in this interface:

- ❖ UP/DOWN: Observe event lists of other pages.
- ❖ CURSOR: Move the cursor to select an event in the list.
- ❖ RENAME: Rename the selected Arr. event. Turn the knob until your necessary name appears, then press the knob.
- ❖ WAVE: Press this button to display the waveform of the selected arrhythmia event, time of occurrence and the parameters at this time in the window.



In the arrhythmia waveform recall interface:

- ❖ UP/DOWN: To observe waveforms of other Arrhythmia events.
- ❖ CURSOR: To observe the whole 8s waveform of Arrhythmia event.
- ❖ RECORD: To print out displayed waveform of Arrhythmia event.
- ❖ EXIT: To return to ARR RECALL menu listing Arrhythmia events.

**NOTE:**

- If there are more than 60 Arrhythmia events, the latest ones will be retained.

#### 10.8.4 PVCs Alarms and Prompt messages

Among physiological alarms, those belonging to the type that the parameter has exceeded the limits may activate the recorder to automatically output the

parameters and related measured waveforms when the alarms occur on the condition that the alarm record switch in related menu is On. Possible physiological alarms and technical alarms during PVCs measurement are listed as below.

**Physiological alarm:**

Message	Cause	Alarm Level
PVCS ALM	PVCs measuring value is above the upper alarm limit.	User-selectable

**Arrhythmia alarm**

The alarm is triggered when an Arrhythmia occurs. If the ALM is ON, the alarm sounds and the alarm indicator flashes. If the REC is ON, the alarm record will be printed out (the ECG waveform of the channel being analysed 4 seconds prior to and after the alarm). Alarms and prompt messages related to arrhythmia analysis are listed as below:

**Physiological alarm:**

Message	Applicable Patient Type	Occurring Condition	Alarm Level
ASYSTOLE	All patients	No QRS complex is detected for consecutive 6 seconds.	User-selectable
VFIB /VTAC	Without pacemaker	Fibrillation wave for consecutive 4 seconds, or the number of continuous ventricular beats is larger than the upper limit of cluster ventricular beats ( $\geq 5$ ). The RR interval is less than 600ms.	User-selectable

VT>2	Without pacemaker	3 < the number of cluster PVCs < 5	User-selectable
COUPLET	Without pacemaker	2 consecutive PVCs	User-selectable
BIGEMINY	Without pacemaker	Vent Bigeminy	User-selectable
TRIGEMINY	Without pacemaker	Vent Trigeminy	User-selectable
R ON T	Without pacemaker	HR is less than 100, R-R interval is less than 1/3 of the average interval, followed by a compensatory pause of 1.25 times of the average R-R interval (the next R wave advances onto the previous T wave).	User-selectable
PVC	Without pacemaker	Single PVC not belonging to the type of above mentioned PVCs.	User-selectable
TACHY	All patients	5 consecutive QRS complex , RR interval is less than 0.5s.	User-selectable
BRADY	All patients	5 consecutive QRS complex, RR interval is longer than 1.5s.	User-selectable
MISSED BEATS	Without pacemaker	When HR is less than 100 beats/min, no heart beat is tested during the period 1.75 times of the average RR interval; or When HR is larger than 100 beats/min, no beat is tested with 1 second.	User-selectable

PNP	With pacemaker	No QRS complex and pacing pulse are available during the period 1.75 times of the average R-R interval (only considering patients with pacemaker.)	User-selectable
PNC	With pacemaker	When pacing pulse is available, no QRS complex exists during the period 1.75 times of the average RR interval (only considering patients with pacemaker.)	User-selectable

Applicable patient type: "All patients" refers to perform Arr.analysis on patients either with pacemakers or without pacemakers.

"Without pacemaker": refers to perform Arr. Analysis only on the patients without pacemakers.

"With pacemaker": refers to perform Arr. Analysis only on the patients with pacemakers.

Prompt message:

Message	Cause	Alarm Level
ARR LEARNING	The QRS template building required for Arr. Analysis is in process.	No alarm

NOTE:

- Arrhythmia name displays in the alarm area.

## Chapter 11 RESP Monitoring

### 11.1 Introduction

Measurement method: chest impedance. When the patient breathes, the thoracic activity causes a change in the thoracic impedance between the two ECG electrodes. The monitor produces a respiratory wave on the screen by measuring the impedance change (due to the movement of the thorax), then it calculates the respiration rate based on the waveform cycle.

### 11.2 Safety information

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#### WARNING

- Respiratory measurement does not recognize the reason of suffocation, it will only give alarm if no next respiration is checked within the predetermined time after the last breath, so it can not be used for diagnostic purposes.
- 

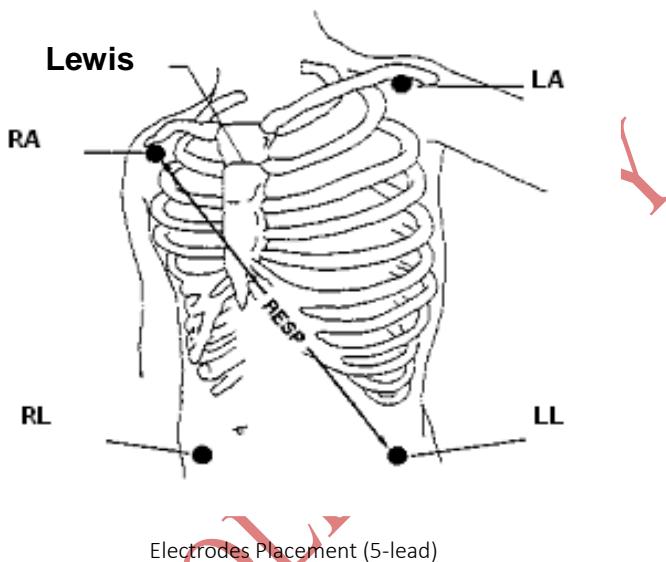
### 11.3 Placement for RESP electrode

As the skin is a bad conductor, in order to get a good respiration signal, process the skin where the electrode is placed is necessary. See "ECG Monitoring" chapter for skin processing method.

For RESP monitoring, it is not necessary for additional electrodes, however, the electrode placement is important. Some patients, due to their clinical condition, expand their chest laterally, causing a negative intrathoracic pressure. In these cases it is better to place the two RESP electrodes laterally in the right axillary and left lateral chest areas at the maximum point of breathing movement to optimize the respiratory waveform.

**NOTE:**

- The RESP monitoring is not recommended to be used on patients who are very active, as this can cause false alarms.



Electrodes Placement (5-lead)

**NOTE:**

- Placing the red and white electrodes diagonally to obtain the optimal respiration waveform. Avoid the liver area and the ventricles of the heart in the line between the RESP electrodes so as to avoid cardiac overlay or artifacts from pulsating blood flow. This is particularly important for neonates.

#### 11.4 RESP SETUP

Press RESP hot key on the screen to "RESP SETUP" interface:

- ALM REC: select "ON" to enable report printing upon RESP alarm.
- SWEEP: 6.25 mm/s, 12.5 mm/s, 25.0 mm/s
- WAVE AMP: RESP waveform can be amplified for displaying, amplification

factor:  $\times 0.25$ ,  $\times 0.5$ ,  $\times 1$ ,  $\times 2$ ,  $\times 4$ .

- Measurement mode: LL-RA or LA-RA
- RESP alarm setup:

Enter the initial password "70808" to set the following contents:

- ◆ ALM: when RESP alarm occurs, the system will prompt and store the alarm information after selecting "ON", it will not alarm when selecting "OFF", and "" will appear in parameter area.
- ◆ ALM LEV: HIGH, MED and LOW, high represents the most serious alarm.
- ◆ ALM HI: set the upper alarm limit.
- ◆ ALM LO: set the lower alarm limit.
- ◆ APNEA ALM: set the time of judging an apnea case. Range: 10 ~ 40 s, increase / decrease 5 s after every rotating.

- DEFAULT: select it to "RESP DEFAULT CONFIG" menu, in which the user may select "FACTORY DEFAULT CONFIG" or "USER DEFAULT CONFIG". After selecting any of the items and exiting the dialog box, the system will pop up the dialog box asking for confirmation

## 11.5 RESP Alarm message

Among physiological alarms, those belonging to the type that the parameter has exceeded the limits may activate the recorder to automatically output the parameters and related measured waveforms when the alarms occur on the condition that the alarm record switch in the related menu is On.

Tables below describe the possible physiological alarms, technical alarms and prompt messages occurring during RESP measurement.

Physiological alarms:

Message	Cause	Alarm Level
RR HI	RESP measurement value is higher than upper alarm limit.	User-selectable
RR LOW	RESP measuring value is lower than lower alarm limit.	User-selectable
RESP APNEA	RESP can not be measured within specific time interval.	HIGH

Technical alarms:

Message	Cause	Alarm Level	Remedy
RESP LEAD OFF	RA, RL or LL falls off.	MED	Make sure all electrodes, leads and cables are connected normally.

## Chapter 12 SpO<sub>2</sub> Monitoring

### 12.1 Introduction

SpO<sub>2</sub> Plethysmogram measurement is employed to determine the oxygen saturation of hemoglobin in the arterial blood. If, for example, 97% hemoglobin molecules in the red blood cells of the arterial blood combine with oxygen, then the blood has a SpO<sub>2</sub> oxygen saturation of 97%. The SpO<sub>2</sub> numeric on the monitor will read 97%. The SpO<sub>2</sub> numeric shows the percentage of hemoglobin molecules which have combined with oxygen molecules to form oxyhemoglobin. The SpO<sub>2</sub>/PLETH parameter can also provide a pulse rate signal and a plethysmogram wave.

#### How the SpO<sub>2</sub> / PLETH Parameter Works

- Arterial oxygen saturation is measured by a method called pulse oximeter. It is a continuous, non-invasive method based on the different absorption spectra of reduced hemoglobin and oxyhemoglobin. It measures how much light, sent from light sources on one side of the sensor, is transmitted through patient tissue (for example, a finger), to a receiver on the other side. The sensor measurement wavelengths are nominally 660nm for the Red LED and 880nm for Infrared LED. Maximum optical power output for the Red LED is 6.65 mW and the Infrared LED is 6.75 mW. Optical sensors as the light-emitting components, will bring influence to other medical devices applied the wavelength range. This information may be useful for clinicians who carry out optical therapy.
- The amount of light transmitted depends on many factors, most of which are constant. However, one of these factors, the blood flow in the arteries, varies with time, because it is pulsating. By measuring the light absorption

during a pulsation, it is possible to get the oxygen saturation of the arterial blood. Detecting the pulsation gives a PLETH waveform and pulse rate signal.

- The SpO<sub>2</sub> value and the PLETH waveform can be displayed on the main screen.

## 12.2 Safety information

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### WARNING

- Only the SpO<sub>2</sub> sensor specified in this manual can be used, please use it following the Use Manual, and obey all warnings and precautions.
- Check if the sensor cable is in normal condition before monitoring. After unplugging the SpO<sub>2</sub> sensor cable from the socket, the system shall display the error message "SpO<sub>2</sub> SENSOR OFF" and give the audible alarm.
- Do not use the SpO<sub>2</sub> sensor once the package or the sensor is found damaged. Instead, you shall return it to the vendor.
- ES (Electrosurgery) equipment cable and SpO<sub>2</sub> cable must not be tangled up.
- Prolonged and continuous monitoring may increase the risk of unexpected change of skin condition such as abnormal sensitivity, rubescence, vesicle, repressive putrescence, and so on. It is especially important to check the sensor placement of patient of poor perfusion or immature dermogram by light collimation and proper attaching strictly according to changes of the skin. Check the sensor placement periodically and move it when the skin deteriorates. More frequent examinations may be required for different patients.
- The person who is allergic to silicone or ABS can not use this device.
- The SpO<sub>2</sub> probe accompanying with the monitor is only intended for use in

this monitor. The monitor can only use the SpO<sub>2</sub> probe supplied in this manual. It is the operator's responsibility to check the compatibility of the monitor, probe and extension cord before use, to avoid the patient's injury.

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**NOTE:**

- SpO<sub>2</sub> waveform is not proportional to the pulse volume.
- Some models of functional tester or patient simulator can measure the accuracy of the device that reproduces the calibration curve, but it can not be used to evaluate the accuracy of this device.
- SpO<sub>2</sub> function is calibrated to show functional oxygen saturation.
- The accuracy of pulse rate has been verified by using a patient simulator.
- The PLETH waveforms are not normalized, so the accuracy of the measured values may decrease when the waveform does not tend to be smooth and stable. When the waveform tends to be smooth and stable, the measured value is the best value, and the waveform is the most standard.
- The update time of measurement data is less than 10 seconds, which depends on the PR value. Data averaging and other signal processing have no effect on SpO<sub>2</sub> displaying and data values transmitted.
- The device does not need to be calibrated during maintenance.

### 12.3 SpO<sub>2</sub> Measurement

1. During measuring, make sure that the wearing parts meet the following conditions:
  - ◆ Pulsating blood flow, and circulation perfusion is well.
  - ◆ The thickness does not change, the thickness change will cause the mismatch for the sensor and wear parts.
2. PR will be displayed only under the following situations:

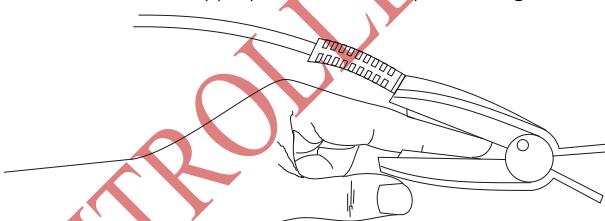
- Select "HR FROM" as "SpO<sub>2</sub>" or "BOTH" in the ECG SETUP menu.
- Select "HR FROM" as "AUTO" in the ECG SETUP menu and there is no ECG signal.

**NOTE:**

- Make sure the fingernail covers the light.
- The SpO<sub>2</sub> value is always displayed in a fixed place.
- The declaration for SpO<sub>2</sub> accuracy is supported by a clinical study covering the entire range.

#### 12.4 Monitoring steps

1. Switch on the monitor.
2. Insert the sensor plug into the SpO<sub>2</sub> jack.
3. Attach the sensor to the appropriate site of the patient finger.



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**WARNING**

- Check the wearing parts once per 2 to 3 hours to ensure the good skin texture and proper light alignment. If the skin texture changes, move the sensor to another location. It is best to change the wearing parts once per 4 hours.

**NOTE:**

- Do not use photoelectric oximeters and SpO<sub>2</sub> sensors during magnetic resonance imaging (MRI) scanning, as the induced current may cause burns.

## 12.5 Measurement Limitations

During measuring, the measurement accuracy can be affected by:

- High-frequency electrical interference, such as the interference created by the host system, or interference from external sources, for example electrosurgical apparatus connected to the system.
- Diagnostic test.
- Electrosurgery unit.
- Intravascular dye injections
- Electromagnetic field effects, such as nuclear magnetic resonance equipment.
- Excessive patient movement(patient moves actively or passively).
- Improper sensor installation or incorrect contact position of the patient
- Place the sensor on an extremity that has a blood pressure cuff, arterial catheter, or intravascular line.
- Significant concentrations of non-functional hemoglobin, such as carboxyhemoglobin(COHb) and methemoglobin(MetHb).
- Bad circular perfusion of the part being measured
- For some special patients, it should be a more prudent inspecting in the measurement part. The sensor can not be clipped on the edema and tender tissue.
- When the device is carried from cold environment to warm or humid environment, please do not use it immediately.
- As to the fingers which are too thin or too cold, it would probably affect the normal measurement of the patients' SpO<sub>2</sub> and pulse rate, please clip the thick finger such as thumb and middle finger deeply enough into the probe.
- Make sure the optical path is free from any optical obstacles like rubberized

fabric, to avoid inaccurate measurement.

- Excessive ambient light may affect the measurement result. It includes fluorescent lamp, dual ruby light, infrared heater, direct sunlight, etc.
- The SpO<sub>2</sub> sensor and photoelectric receiving tube should be arranged in a way with the subject's arteriole in a position there between.
- Testee can not use enamel or other makeup.
- Testee's fingernail can not be too long.

## 12.6 SpO<sub>2</sub> SETUP

Turn the knob to move the cursor onto the SpO<sub>2</sub> hot key in the Parameter area, push the knob to "SpO<sub>2</sub> SETUP" menu.

- ALM REC: pick "ON", the system will output alarm information when SpO<sub>2</sub> alarm occurs.
- SWEEP: 12.5mm/s, 25.0 mm/s
- SpO<sub>2</sub> alarm setting

Set the following contents after entering the initial password "70808":

- ◆ SpO<sub>2</sub> ALM: pick "ON", the system will give alarm prompt and store alarm information when SpO<sub>2</sub> alarm occurs; pick "OFF", the system will not

give alarm and instead display a  beside "SpO<sub>2</sub>".

- ◆ ALM LEV: set the alarm level, selectable from HI, MED and LO. HIGH represents the most serious case.

- ◆ SpO<sub>2</sub> ALM HI and SpO<sub>2</sub> ALM LO: SpO<sub>2</sub> alarm is activated when the result exceeds set SpO<sub>2</sub> ALM HI value

or falls below SpO<sub>2</sub> ALM LO value.

- ◆ PR ALM: pick "ON", the system will give alarm prompt and store alarm information when PR alarm occurs.

- ◆ PR ALM HI: PR alarm is activated when the pulse rate exceeds set PR ALM HI value.
  - ◆ PR ALM LO: PR alarm is activated when the PR falls below PR ALM LO value.
- To further detect alarms for individual measurement parameters, perform a measurement check on yourself or by using the simulator, adjust the alarm limits setting and check if the correct alarm response is triggered.

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#### WARNING

- Set the upper limit of SpO<sub>2</sub> alarm to completely equal to off-state upper limit alarm. High-oxygen level will cause fibrous fibrosis for preterm infants. Therefore, the upper limit of the SpO<sub>2</sub> alarm must be carefully chosen according to accepted clinical practice.

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#### NOTE:

- The upper and lower limit of SpO<sub>2</sub> alarm will be displayed continuously in the SpO<sub>2</sub> parameter area.
- DEFAULT: select it to "SpO<sub>2</sub> DEFAULT CONFIG" menu, in which you can select "FACTORY DEFAULT CONFIG" or "USER DEFAULT CONFIG". After selecting one item and exiting the interface, the system will pop up the dialog box asking for your confirmation.

### 12.7 SpO<sub>2</sub> Alarm message

#### NOTE:

- There is no alarm delay for SpO<sub>2</sub>.

#### SpO<sub>2</sub> alarm information

When the alarm switches are set to "ON" in relevant menus, the physiological

alarms caused by the parameter exceeding the alarm limit may possibly trigger the recorder to automatically output the alarm parameter value and corresponding waveforms.

Tables below describe the possible physiological alarms, technical alarms and prompt messages occurring during SpO<sub>2</sub> measurement.

Physiological alarm:

Message	Cause	Alarm Level
SpO <sub>2</sub> HI	SpO <sub>2</sub> measurement value is higher than the upper limit of alarm.	User-selectable
SpO <sub>2</sub> LOW	SpO <sub>2</sub> measurement value is lower than the lower limit of alarm.	User-selectable
PR HI	PR measurement value is higher than the upper limit of alarm.	User-selectable
PR LOW	PR measurement value is lower than the lower limit of alarm.	User-selectable

Technical alarms:

Message	Cause	Alarm Level	Remedy
SpO <sub>2</sub> SENSOR OFF	SpO <sub>2</sub> sensor may be disconnected from the patient or the monitor.	LOW	Make sure the sensor is placed in patient's finger or other parts, and the connection between the monitor and the cables is well.
SpO <sub>2</sub> COMM	SpO <sub>2</sub> module failure or	HIGH	Stop using the measuring function of SpO <sub>2</sub> module, notify

ERR	communication error.		biomedical engineer or our service staff.
SpO <sub>2</sub> SENSOR FAULT	Inserting the probe falsely will cause the short circuit for SpO <sub>2</sub> circuit or SpO <sub>2</sub> probe cable.	HIGH	Check the type of SpO <sub>2</sub> probe or replace the SpO <sub>2</sub> probe.

Prompt message:

Message	Cause	Alarm Level
SpO <sub>2</sub> SEARCHING PR	SpO <sub>2</sub> module is searching for pulse.	No alarm
SpO <sub>2</sub> SEARCH TIMEOUT	SpO <sub>2</sub> module cannot detect SpO <sub>2</sub> signal for a long time.	HIGH

## Chapter 13 NIBP Monitoring

### 13.1 Introduction

Measurement method: Oscillometry. It is applicable for adult, pediatric and neonate. In order to know how the Oscillometry works, we compare it with auscultatory method:

- Auscultatory method: the doctor listens the blood pressure by the stethoscope, to obtain the systolic pressure and diastolic pressure. When the artery pressure curve is normal, the mean pressure can be calculated by the systolic pressure and diastolic pressure.
- Oscillometry: the blood pressure can not be listened by the monitor, it measures the vibration amplitude of cuff pressure. Cuff vibration appears when the blood pressure changes, the cuff pressure corresponding to the maximum amplitude is the mean pressure, the systolic and diastolic pressure can be calculated by the mean pressure.

In a word, the auscultatory method measures the systolic and diastolic pressure, then calculates the mean pressure. And the Oscillometry measures the mean pressure, then calculates systolic and diastolic pressure.

The clinical meaning for NIBP measurement must be determined by the physician. When measuring during in representative patients group, compare the blood pressure values measured by the device and auscultatory method, its accuracy meets the requirements specified in IEC 80601-2-30:2009.

### 13.2 Safety information

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#### WARNING

- Before measuring, make sure that the monitoring mode and cuff type you

selected are appropriate for your patient(adult, pediatric or neonate). As false settings may imperil patient's safety, higher adult settings are not suitable for pediatric and neonate.

- You must not perform NIBP measurement on patients with sickle-cell disease or under any condition which the skin is damaged or expected to be damaged.
- For the patients with severe clotting mechanism abnormality, please determine whether automatically measure the blood pressure according to the clinical evaluation, as the rub position between the limb and cuff will have the risk of producing hematoma.
- Do not apply the cuff to a limb that has an intravenous infusion or catheter. This could cause tissue damage around the catheter when infusion is slowed or blocked during cuff inflation.
- NIBP measurement can be performed during electrosurgery and defibrillator discharge, as the device has the function of protecting burn patients.
- The device can be used in existence of electrosurgical equipment, but when using them together, user(doctor or nurse) should guarantee the patient's safety.
- Make sure that the air conduit connecting the blood pressure cuff and the monitor is neither blocked nor tangled.
- If liquid is inadvertently splashed on the device or its accessories, or may enter the conduit or inside the monitor, please contact with the maintenance department in hospital.

---

NOTE:

- If you are in doubt about the accuracy of any reading(s), check the patient's vital signs by an alternative method before checking the functioning of the

monitor.

- When the alarm prompt information for low battery appears, it is not recommended to start NIBP measurement. As in this circumstance, it may cause device shutdown.

### 13.3 Measurement Limitations

NIBP measurement can not be done on the patients with extreme heart rate(lower than 40 bpm or higher than 240 bpm) or connecting with heart-lung machine. The measurement may be inaccurate or can not be done in the following conditions:

- Patient Movement

Measurement will be unreliable or may be impossible if the patient is moving, shivering or having convulsions. As these conditions may interfere the detection of the arterial pressure pulsation, and the measurement time will be prolonged.

- Cardiac Arrhythmia's

Measurement will be unreliable and may be impossible if the patient has irregular heartbeat arisen from cardiac arrhythmia, and the measurement time will be prolonged.

- Pressure Change

Measurement will be unreliable and may be impossible if the patient's blood pressure is changing rapidly over the period of time during which the arterial pressure pulsation are being analyzed to obtain the measurement values.

- Severe Shock

If the patient is in severe shock or hypothermia, measurements will be unreliable since the decrease for the blood flowed to the peripheries will cause the

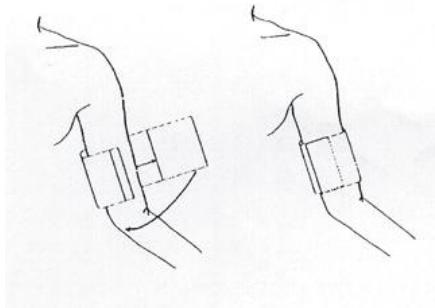
reduction of artery pulsation.

- Fat patient

The thick fat layer under the limb will decrease the measurement accuracy, as the vibration from artery can not arrive to the cuff which is arisen from the fat damping.

#### 13.4 Measurement steps

1. Confirm the patient type, if it is false, please change "Patient type" in "PATIENT SETUP" of "SYSTEM MENU".
2. Connect the airway tube with the NIBP interface of the device, then switch on the device.
3. Select the cuff, make sure the cuff is completely deflated, then apply the cuff to the patient's arm or leg following the instructions below.
  - Confirm the limb perimeter of the patient.
  - Apply the cuff to the patient's arm or leg, and make sure that the symbol " $\phi$ " exactly locates to the artery. Ensure that the cuff is not wrapped too tightly around the limb, otherwise it will cause discoloration or ischemia of the limb. Check the cuff edge is in the range marked <->, otherwise please change an appropriate cuff.
  - The width of the cuff should be either 40% of the limb circumference (50% for neonates) or 2/3 of the upper arm length. The inflatable part of the cuff should be long enough to encircle 50-80% of the limb. The wrong size of cuff can cause erroneous readings. If the cuff size has problem, then use a larger cuff.



4. Connect the cuff to the airway tube. Make sure that the airway tube is neither blocked nor tangled.
5. Select a measurement mode in "NIBP SETUP" interface. Refer to the following paragraphs "Operation Hints" for Details
6. Press "NIBP" button on the front panel to start a measurement.

**NOTE:**

- When measuring NIBP, keep subject and subject's limbs still, not move and talk.

### 13.5 Operation hints

1. Manual operation
  - Select "MANUAL" in "INTERVAL" item of "NIBP SETUP" interface, then press "NIBP" button on the front panel to start a manual measurement.
  - During the idle time of auto measuring process, press "NIBP" button on the front panel to start a manual measurement. Press "NIBP" button again to stop manual measurement and the system continues auto measuring.

### 2. Auto measuring

Select a interval value in "INTERVAL" item of "NIBP SETUP" interface to perform auto measurement., then press "NIBP" button on the front panel to start the first measurement, after finishing, the system will automatically measure according to

the interval time.

### 3. Continuous measuring

Select "CONTINUAL" item in "NIBP SETUP" interface to start a continuous measurement. The process will continue 5 minutes.

### 4. Stop measuring

During measuring, press "NIBP" button on the front panel to stop measuring.

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#### WARNING

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- In auto or continuous mode, if the time is too long, then the limb rubbed with the cuff may appear purpura, ischemia and nerve injury. So when monitoring the patient, patient's limb color, warmth and sensitivity should be checked frequently. Once any abnormality appears, please replace the cuff location or stop the NIBP measurement.
- 

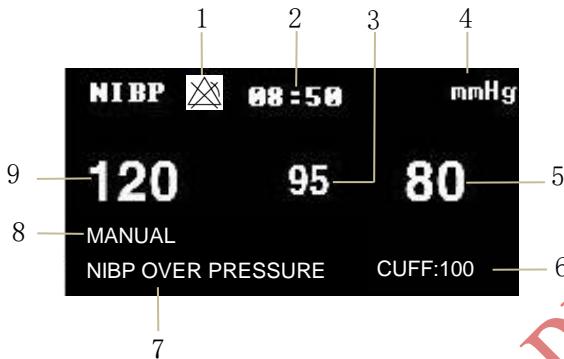
### 13.6 Amend results

Keep the limb to be measured and the patient's heart on one horizontal position. Otherwise amend the measurement results by the following methods:

- If the cuff is higher than the horizontal position of the heart, then the value should add 0.75 mmHg(0.10 kPa) after the displayed value.
- If the cuff is lower than the horizontal position of the heart, then the value should subtract 0.75 mmHg(0.10 kPa) after the displayed value.

### 13.7 NIBP display

There is no waveform for NIBP measurement, it only displays the NIBP measurement results. The following figure is only used for reference, your device may display a different interface.



1. Alarm is off
2. Measurement time
3. Mean pressure
4. Unit: mmHg or kPa
5. Diastolic pressure
6. Current cuff pressure
7. Prompt information area: display prompt information related to NIBP.
8. Measurement mode
9. Systolic pressure

### 13.8 NIBP SETUP

Move the cursor to the NIBP hot key, press it to enter the "NIBP SETUP" interface.

- ALM REC: select "ON" to enable report printing upon NIBP alarm.
- Unit: mmHg or kPa
- INTERVAL

Interval time in AUTO mode: 1/2/3/4/5/10/15/30/60/90/120/240/480/960 minutes. After selecting the interval time, the information "Please start" will appear in the NIBP prompt area, then press "NIBP" button to start the first auto measurement. Select "MANUAL" in interval time to stop auto measuring and

enter to manual measurement.

#### ■ INFLATION

Press this button to select the initial pressure value for the cuff next time, there are different pre-inflation value ranges in different default configurations, as shown in the following table.

Default configurations	Default inflation value (mmHg/kPa)	Selectable inflation value in manual mode in NIBP menu(mmHg/kPa)
FACTORY DEFAULT ADU CONFIG	150	80/100/120/140/150/160/180/200/220/240
FACTORY DEFAULT PED CONFIG	100	80/100/120/140/150/160/180/200
FACTORY DEFAULT NEO CONFIG	70	60/70/80/100/120
USER DEFAULT ADU CONFIG	150	80/100/120/140/150/160/180/200/220/240
USER DEFAULT PED CONFIG	100	80/100/120/140/150/160/180/200
USER DEFAULT NEO CONFIG	70	60/70/80/100/120

Press "MENU" button to enter "SYSTEM MENU" menu, then select a factory or user configuration in "DEFAULT" menu, after configuration, return to the main interface to select NIBP hot key to enter "NIBP SETUP" menu. Here the initial value for "Inflation" is the initial inflation pressure value corresponding to default configuration, as shown in the above table. Move the cursor to the "Inflation"

item and press it, inflation value range(as shown in the above table) in MANUAL mode can be seen.

**NOTE:**

- "Inflation" is used to help user select the cuff inflation pressure next time, but the subsequent inflation is the measurement value of last systolic pressure based on the same patient. The system memorizes the value, which can shorten the measurement time of the same patient and increase the measurement accuracy.
- If user only sets the "Patient type" in "PATIENT SETUP" interface, does not perform any selection in "DEFAULT", the system will operate according to the initial setting of relative module parameter in "Patient type". The change of default type setting in "DEFAULT" will alter the "Patient type" in "PATIENT SETUP" interface.
- NIBP alarm setting

Enter the initial password "70808" to set the following contents:

- ◆ AIM: when pressure alarm occurs, the system will prompt and store the alarm information after selecting "ON", it will not alarm when selecting "OFF", and "" will appear in parameter area.
- ◆ ALM LEV: HIGH, MED and LOW, "HIGH" represents the most serious alarm.
- ◆ Pressure alarm is set according to the HIGH and LOW limits, alarm is activated when the pressure is higher than the HIGH limit or lower than the LOW limit. Alarm for systolic pressure, mean pressure and diastolic pressure can be set separately.
- RESET

Restore measurement status of the pressure pump. Press this button to restore the initial settings of the pressure pump. When the pressure pump does not work properly and the system fails to give prompt information for the problem, press this button to activate self-test procedure, thus restore the system from abnormal performance.

■ CONTINUAL

Start a continuous measurement, after selecting it, the menu will automatically disappears and measure continuously.

■ CALIBRATE(NIBP pressure calibration )

NIBP pressure calibration should be performed once per two years at least or once when you thought that the reading is inaccurate.

Prepared materials:

- Standard manometer
- Metal container(500 ml)
- Spheroidal air pump
- Airway tube
- T-shape connector

Procedures of the Pressure Transducer Calibration:

Replace the cuff with a metal container with a capacity of  $500\text{ ml} \pm 5\%$ . Connect a calibrated standard manometer, spheroidal air pump(error less than 0.8 mmHg) and airway tube to the NIBP cuff jack of the module by a T-shape connector. Set the monitor in "CALIBRATE" mode. Inflate the pressure in the metal container to 0, 50 and 200 mmHg by spheroidal air pump separately. The difference between the indicated pressure of the standard manometer and the monitor will not exceed 3 mmHg. Otherwise, please contact our customer service.

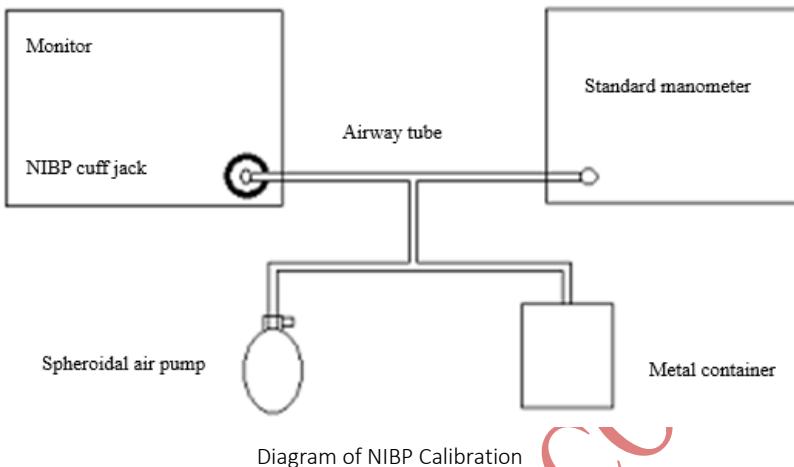


Diagram of NIBP Calibration

■ PNEUMATIC:

It is mainly used to check whether the airtight condition of the air circuit is good. If the test passes, the system will not prompt any information. Otherwise it will prompt corresponding information in NIBP information area. NIBP air leakage test should be performed once per two years at least or once when you thought that the reading is inaccurate.

Prepared materials:

- ◆ Adult cuff: one
- ◆ Airway tube: one
- ◆ Cylinder: one

Procedure of the air leakage test:

1. Set the "Patient type" to "Adult".
2. Connect the cuff with the NIBP cuff jack.
3. Wrap the cuff around the cylinder of an appropriate size.

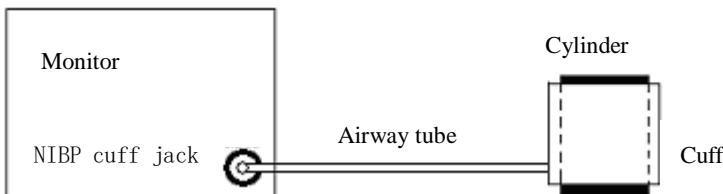


Diagram of NIBP Air Leakage Test

4. Select "PNEUMATIC" in NIBP menu, then the information "Pneum testing..." will display in the NIBP parameter area.
5. The system will automatically inflate to 180 mmHg.
6. The system will automatically deflate after about 20s, it indicates that the air leakage test has finished.
7. If no prompt information appears in NIBP parameter area, it indicates that the airway is in good situation and no air leaks exist. However if the prompt information "NIBP PNEUMATIC LEAK" appears, it indicates that the airway may have air leaks. In this case, the user should check whether the connection is loose. After confirming properconnections, the user should re-perform the pneumatic test.

If the failure prompt still appears, please contact the manufacturer for maintenance.

#### **WARNING**

- This pneumatic test other than being specified in the EN 1060-1 standard is to be used by the user to simply determine whether there are air leaks in the NIBP airway. If at the end of the test, the system prompts that the NIBP airway has air leaks, please contact the manufacturer for maintenance.

- DEFAULT: Select "DEFAULT" to enter "NIBP DEFAULT CONFIG" interface, the user may select "FACTORY DEFAULT CONFIG" or "USER DEFAULT CONFIG". After selecting, the system will prompt for your confirmation.

### 13.9 NIBP Calibration

When the user can not calibrate the NIBP, please contact with the maintenance personnel. The cuff pressure transducer should be maintained by the qualified service personnel, and it should be checked and calibrated once per two years at least.

### 13.10 NIBP Alarm Message

Physiological alarm belongs to the alarm which triggers by the parameters exceeding the limits, which may activate the recorder to automatically output the parameters and related measured waveforms when the alarms occur on the condition that the alarm record switch in the related menu is On.

Tables below describe the possible physiological alarms, technical alarms and prompt messages occurring during NIBP measurement.

Physiological alarms:

Message	Cause	Alarm Level
SYS HI	NIBP SYS measuring value is above upper alarm limit.	User-selectable
SYS LOW	NIBP SYS measuring value is below lower alarm limit.	User-selectable
DIA HI	NIBP DIA measuring value is above upper alarm limit.	User-selectable
DIA LOW	NIBP DIA measuring value is below lower alarm limit.	User-selectable

	alarm limit.	
MEAN HI	NIBP MAP measuring value is above upper alarm limit.	User-selectable
MEAN LOW	NIBP MAP measuring value is below lower alarm limit.	User-selectable

Technical alarms(display in the prompt area below NIBP value):

Message	Cause	Alarm Level	Remedy
NIBP SELF TEST ERROR	Transducer or other hardware of NIBP module is incorrect.	HIGH	Stop using measuring function of NIBP module, notify biomedical engineer or Our service staff.
NIBP COMM ERR	Communication with NIBP module is failed.	HIGH	If failure persists, stop using measuring function of NIBP module, notify biomedical engineer or Our service staff.
NIBP LOOSE CUFF	Cuff is not properly wrapped or no cuff exists.	LOW	Properly wrap the cuff.
NIBP AIR LEAK	Cuff, hose or connector is damaged.	LOW	Check and replace the leaking parts, if required, notify biomedical engineer or Our service staff.
NIBP AIR PRESSURE	Stable pressure value is not	LOW	Check if the hoses are tangled, if failure persists, notify

ERROR	available. e.g. hoses are tangled.		biomedical engineer or Our service staff.
NIBP WEAK SIGNAL	Cuff is too loose or patient pulse is too weak.	LOW	Use other methods to measure blood pressure.
NIBP RANGE EXCEEDED	Measurement range exceeds the specified upper limit.	HIGH	Reset NIBP module, if failure persists, stop using measuring function of NIBP module, notify biomedical engineer or Our service staff.
NIBP EXCESSIVE MOTION	Affected by arm motion, signal noise is too large or pulse rate is not regular.	LOW	Make sure that the patient under monitoring is motionless.
NIBP OVER PRESSURE	Pressure has exceeded the specified upper safety limit.	HIGH	Measure again, if failure persists, stop using measuring function of NIBP module and notify biomedical engineer or Our service staff.
NIBP SIGNAL SATURATED	Excessive motion	LOW	Stop the patient from moving.
NIBP PNEUMATIC LEAK	During pneumatic test, leak is detected.	LOW	Check and replace the leaking parts, if required, notify biomedical engineer or Our service staff.

NIBP SYSTEM FAILURE	Operation of blood pressure pump system is failed.	HIGH	Stop using measuring function of NIBP module, notify biomedical engineer or Our service staff.
NIBP CUFF TYPE ERROR	Cuff type does not comply with the patient type.	LOW	Select an appropriate cuff type
NIBP TIME OUT	Measurement time has exceeded 120 seconds (adult) or 90 seconds (neonatal).	HIGH	Measure again or use other measurement methods.
NIBP ILLEGALLY RESET	Abnormal module reset	HIGH	Reset again.
MEASURE FAIL	The system cannot perform measurement, analysis or calculation during measuring.	HIGH	Check the cuff. Make sure that the patient under monitoring is motionless. Measure again.

Prompt message: (display in the prompt area below NIBP value)

Message	Cause	Alarm Level
Manual measure...	During manual measuring mode.	No alarm

Cont measuring...	During continuous measuring mode.
Auto measuring...	During automatic measuring mode.
Please start	After selecting interval time in MENU
Measurement over	Press NIBP key during measuring to stop measuring.
Calibrating...	During calibrating
Calibration over	Calibration over
Pneum testing...	During pneumatic test
Pneum test over	pneumatic test over
Resetting...	NIBP module in resetting
Reset failed	NIBP module reset failed

## Chapter 14 TEMP Monitoring

### 14.1 Introduction

Two TEMP probes can be used together to obtain 2 temperature data, via comparing, the temperature difference can be obtained.

### 14.2 Safety information

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#### WARNING

- Verify whether the probe cable is normal before monitoring. Unplug the temperature probe cable from the socket, the screen will display the error message “T1/T2 TEMP OFF” and the audible alarm is activated.
  - Take and place the temperature and cable carefully, and they should be rolled to loose loop when not used. If internal electric wires are pulled too tight, the mechanical damage will appear.
  - The calibration of the temperature measurement is necessary for every two years (or as frequently as dictated by your Hospital Procedures Policy). When you need calibrate the temperature measurement, contact the manufacturer please.
- 

### 14.3 Measurement

Measurement steps:

1. Select an appropriate TEMP probe according to patient type and measurement requirement.
2. Insert the probe cable into the TEMP jack directly.
3. Attach the TEMP probe to the patient properly.
4. Confirm that the alarm settings are suitable for the patient.

**NOTE:**

- Disposable TEMP probe can only be used once for one patient.
- The self-test of the temperature measurement is performed automatically once per 30s during the monitoring. The test procedure lasts about 1s, which does not affect the normal measurement of the temperature monitoring.

#### 14.4 TEMP SETUP

Move the cursor to the TEMP hot key, then press the button to enter to "TEMP SETUP" menu.

- ALM REC: Select "ON" to enable report printing upon TEMP alarm.
- TEMP unit: °C or °F
- TEMP alarm setting

After entering the initial password "70808", the following contents can be set:

- ◆ ALM: pick "ON" to enable prompt message and data record during the TEMP alarm; pick "OFF" to disable the alarm function, and prompt the  symbol beside TEMP area.
- ◆ ALM LEV: set the alarm level, three options: HIGH, MED or LOW.
- ◆ Alarm for T1, T2 and TD occurs when the measured temperature exceeds set alarm high limit or falls below alarm low limit.
- DEFAULT: select "DEFAULT" to enter "TEMP DEFAULT CONFIG" interface, the user may select "FACTORY DEFAULT CONFIG" or "USER DEFAULT CONFIG".

After selecting, the system will prompt the user to confirm, then exit.

#### 14.5 TEMP Alarm message

The alarm which triggers by the parameters exceeding the limits, which may

activate the recorder to automatically output the parameters and related measured waveforms when the alarms occur on the condition that the alarm record switch in the related menu is On. Tables below describe the possible physiological alarms, technical alarms and prompt messages occurring during TEMP measurement.

Physiological alarms:

Message	Cause	Alarm Level
T1 HI	Measuring value of channel 1 is above upper alarm limit.	User-selectable
T1 LOW	Measuring value of channel 1 is below lower alarm limit.	User-selectable
T2 HI	Measuring value of channel 2 is above upper alarm limit.	User-selectable
T2 LOW	Measuring value of channel 2 is below lower alarm limit.	User-selectable
TD HI	Difference between two channels is larger than upper limit.	User-selectable

Technical alarms:

Alarm	Cause	Alarm	Remedy

Message		Level	
T1 SENSOR OFF	Temperature cable of channel 1 may be disconnected from the monitor.	LOW	Make sure that the cable is properly connected.
T2 SENSOR OFF	Temperature cable of channel 2 may be disconnected from the monitor.	LOW	Make sure that the cable is properly connected.

## Chapter 15 IBP Monitoring

### 15.1 Introduction

The monitor can provide 2-channel IBP measurement, generate and display real-time waveform, systolic pressure, mean pressure and diastolic pressure for each channel.

### 15.2 Safety information

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#### WARNING

- When applying the accessories, make sure the accessories selected comply with medical device safety requirements.
  - Disposable IBP transducer should not be reused.
  - The operator should avoid contact with the conductive parts of the appurtenance when it is connected or applied.
  - When the monitor is used with HF surgical equipment, the transducer and the cables must be avoided from conductive connection to the HF equipment. This is to protect against burns to the patient.
  - If any kind of liquid, other than solution to be infused in pressure line or transducer, is splashed on the equipment or its accessories, or enters the transducer or the monitor, contact the Hospital Service Center immediately.
- 

#### NOTE:

- Use only the pressure transducer listed in the User Manual.
- Whether it is a new sensor or a sensor used, it should be calibrated in accordance with hospital procedures.

### 15.3 Monitoring Procedure

1. Insert the pressure sensor cable into the IBP interface.
2. Prepare the rinse solution.
3. Rinse the system, exhaust all air in the pipeline. Make sure there are no air bubbles in the sensor or the value.

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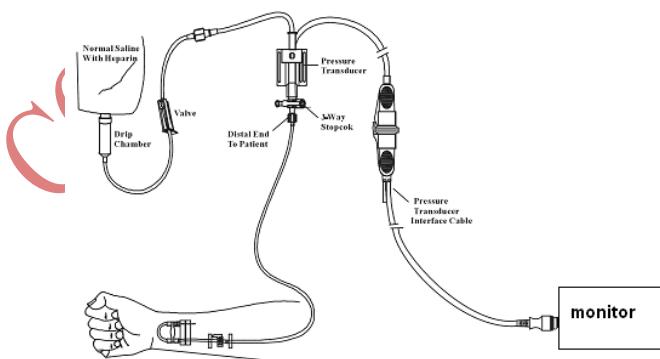
#### WARNING

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- If there are air bubbles in the pipeline, you should rinse the system with the solution. As air bubble may cause false pressure reading.
- 

4. Connect the patient catheter to the pressure pipe.
5. Place the sensor at the same level as the heart, about the middle-axillary line.
6. Select a correct label name.
7. Zero the transducer.
8. After zeroing successfully, turn off the valve from the transducer to atmospheric pressure, and turn on the valve to

the patient.



IBP module placement diagram

#### 15.4 Setting for label name

1. Select the IBP hot key by the cursor.
2. Select an appropriate label name.

Waveform name	Definition
ART	Arterial Blood Pressure
PA	Pulmonary Arterial Pressure
CVP	Center Venous Pressure
RAP	Right Atrial Pressure
LAP	Left Atrial Pressure
ICP	Intracranium Pressure
P1-P2	Expand Pressure

#### 15.5 IBP Menu

Select the IBP hot key on the screen to enter the "IBP(1,2) SETUP" menu shown as following:



The items to be set in the menu include:

- ALM REC: select "ON" to enable alarm prompt and data storage during IBP alarm.

- SWEEP: set the scanning speed of the IBP waveform. Two selections: 12.5 mm/s or 25 mm/s.
- UNIT: mmHg / kPa / cmH<sub>2</sub>O
- FILTER: non filter, smooth, normal.
- SCALE ADJUST: select it to enter "IBP PRESS RULER ADJUST" menu, in which the user may adjust the position of upper scale, lower scale and middle scale displayed on the screen.
- EXPAND PRESSURE: select it to enter "IBP EXPAND PRESS SET" menu, in which the user can set the pressure type of P1 and P2.
- DEFAULT: select it to enter "IBP DEFAULT CONFIG" menu, in which the user may select "FACTORY DEFAULT CONFIG" or "USER DEFAULT CONFIG". After selecting any of the items and exiting the dialog box, the system will pop up the dialog box asking for the user's confirmation.
- IBP Alarm SETUP:

Enter the initial password "70808" to set the following contents:

- ◆ ALM: when IBP alarm occurs, the system will prompt and store the alarm information after selecting "ON", it will not alarm when selecting "OFF", and  will appear in parameter area.
- ◆ ALM LEV: HIGH, MED and LOW.
- ◆ ALM LIMIT SET: select it to enter "IBP Alarm Limit Settings" menu. In this sub-menu, the user can respectively adjust the upper and lower limits of systolic, diastolic and average pressure of channel 1 and channel 2.

In the case of the alarm switch is open, when the systolic blood pressure, mean pressure or diastolic blood pressure is higher than the upper limit or less than the lower limit, the corresponding physiological alarm occurs. Alarm limit can be

adjusted (the step is 1), first select the name to be set, then set the systolic pressure alarm / diastolic pressure alarm / mean pressure alarm.

## 15.6 IBP Scale Setup

IBP PRESS RULER ADJUST			
	HI	LO	VAL
CH1:ART	160	0	82
CH2:CVP	40	0	20
E X I T			
Back to the upper menu.			

The waveform scale displays in the IBP waveform area, the three dotted lines from top to bottom respectively represent the upper scale, reference scale and lower scale of the waveform, which can be set, the steps are as followings:

1. Select "SCALE ADJUST" in "IBP SETUP" interface.
2. Select "HI", "VAL" and "LO" to set the appropriate scale.

### NOTE:

- IBP1 and IBP2 pressure name can be selected from IBP waveform hotkey area.

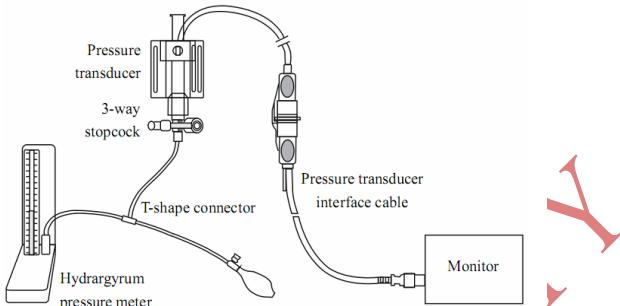
## 15.7 IBP Pressure Zero

The monitor requires a valid zero point to obtain an accurate pressure reading. Please calibrate the sensor according to the requirements of the hospital (at least once a day). The zero operations must be performed in following conditions:

- When using a new sensor or sensor cable.
- When re-connecting the sensor cable and the monitor.
- When the monitor is restarted.
- When you doubt that the monitor pressure reading is inaccurate.

Calibration steps are as followings:

1. Turn off the valve from the 3-way stopcock to the patient.



2. The transducer must be vented to atmospheric pressure via the 3-way stopcock.
3. Take the channel 1 as an example, select "IBP SETUP" → "IBP PRESSURE ZERO" → "CH1 ZERO", then select it to calibrate.
4. When the information "CH1 SUCCESSFUL ZERO." appears, close the valve to the atmospheric pressure and open the valve to the patient.

**NOTE:**

- The user should ensure that the sensor has been calibrated before zeroing, otherwise the device hasn't a valid zero value, which will lead to an inaccurate result.

**Troubleshooting for pressure zeroing**

Cause	Remedy
IBP1 SENSOR OFF, FAIL.	Make sure that the channel 1 has not the prompt of sensor off, then zero again, if the problem exists still, please contact the service personnel.
DEMO, FAIL.	Make sure that the monitor is not in DEMO mode,

	then zero again, if the problem exists still, please contact the service personnel.
PRESSURE OVER RANGE, FAIL	Make sure the valve is vented to atmospheric pressure, then zero again, if the problem exists still, please contact the service personnel.
PULSATILE PRESSURE, FAIL	Make sure that the sensor is not connected to the patient, the valve is vented to atmospheric pressure, then zero again, if the problem exists still, please contact the service personnel.

## 15.8 IBP Calibration

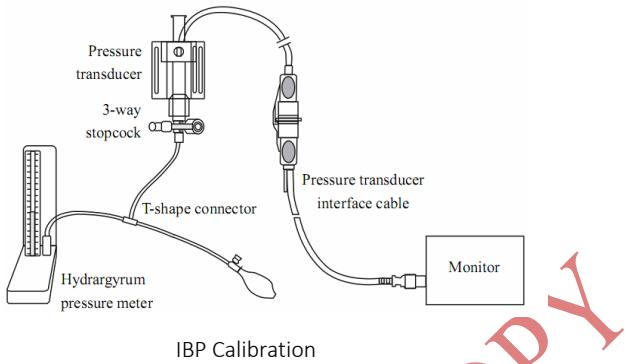
Calibration points for mercury pressure gauge:

Mercury pressure gauge calibration should be carried out when a new sensor is used or in accordance with the period specified by the hospital procedure.

The purpose of the calibration is to ensure that the system provides an accurate measurement. Before starting a calibration by the mercury pressure gauge, a zero procedure must be performed. If you need to perform this procedure by yourself, you need the following equipment:

- Standard sphygmomanometer
- T-shape connector
- Tubing(approximately 25 cm)

The calibration procedure for mercury pressure gauge:



## WARNING

- You must never perform this procedure while the patient is being monitored.
1. Zeroing must be performed before starting the mercury pressure gauge calibration.
  2. Connect the tubing to the sphygmomanometer.
  3. Ensure that the connection to patient is off.
  4. Connect one end of the T-shape connector to the 3-way stopcock, the other end to the gasbag, the third end to the sphygmomanometer.
  5. Open the port of the 3-way stopcock to the sphygmomanometer.
  6. Select the channel to be calibrated in "IBP PRESSURE CALIBRATE" menu, then select the pressure value.
  7. Inflate to make that the sphygmomanometer pressure is close to the pressure value set.
  8. Adjust repeatedly until the value in the menu is equal to the pressure value shown by the mercury calibration.
  9. Press "CALIBRATE" button, the device will begin calibrating.
  10. Wait for the calibrated result. You should take corresponding measures based on the prompt information.

11. After calibrating, disassemble the blood pressure tubing and the attached T-shape connector.

### 15.9 Troubleshooting for Pressure Calibration

The possible reasons for unsuccessful calibration are listed below:

Cause	Remedy
IBP1 SENSOR OFF, FAIL!	Check the connection condition of channel 1 to make sure that it has not the prompt of sensor off, then calibrate again, if the problem exists still, please contact the service personnel.
DEMO, FAIL.	Make sure that the monitor is not in DEMO mode, then calibrate again, if the problem exists still, please contact the service personnel.
PRESSURE OVER RANGE, FAIL	Make sure the calibration value selected is reasonable, then calibrate again, if the problem exists still, please contact the service personnel.
PULSATILE PRESSURE, FAIL	Make sure the current pressure value displayed on the Sphygmomanometer is constant, then calibrate again, if the problem exists still, please contact the service personnel.

### 15.10 Alarm Information and Prompts

#### Alarm Messages

When the alarm switches are set to "ON" in relevant menus, the physiological alarms caused by the parameter exceeding the alarm limit may possibly trigger the recorder to automatically output the alarm parameter value and corresponding waveforms. Tables below describe the possible physiological alarms, technical alarms and prompt messages occurring during IBP measurement.

Physiological alarms:

Message	Cause	Alarm Level
IS1 HI	SYS measuring value of channel 1 is above upper alarm limit.	User-selectable
IS1 LOW	SYS measuring value of channel 1 is below lower alarm limit.	User-selectable
ID1 HI	DIA measuring value of channel 1 is above upper alarm limit.	User-selectable
ID1 LOW	DIA measuring value of channel 1 is below lower alarm limit.	User-selectable
IM1 HI	MAP measuring value of channel 1 is above upper alarm limit.	User-selectable
IM1 LOW	MAP measuring value of channel 1 is below lower alarm limit.	User-selectable
IS2 HI	SYS measuring value of channel 2 is above upper alarm limit.	User-selectable
IS2 LOW	SYS measuring value of channel 2 is below lower alarm limit.	User-selectable
ID2 HI	DIA measuring value of channel 2 is above upper alarm limit.	User-selectable

ID2 LOW	DIA measuring value of channel 2 is below lower alarm limit.	User-selectable
IM2 HI	MAP measuring value of channel 2 is above upper alarm limit.	User-selectable
IM2 LOW	MAP measuring value of channel 2 is below lower alarm limit.	User-selectable

Technical alarms:

Message	Cause	Alarm Level	Remedy
IBP1 SENSOR OFF	IBP cable of channel 1 falls off from monitor.	LOW	Make sure that the cable is properly connected.
IBP2 SENSOR OFF	IBP cable of channel 2 falls off from monitor.	LOW	Make sure that the cable is properly connected.
IBP(1,2) INIT ERR	IBP module failure	HIGH	Stop using the measurement function of IBP module, notify biomedical engineer or Our service staff.
IBP(1,2) INIT ERR1			
IBP(1,2) INIT ERR2			
IBP(1,2) INIT ERR3			
IBP(1,2) INIT ERR4			
IBP(1,2) INIT ERR5			
IBP(1,2) INIT ERR6			
IBP(1,2) INIT ERR7			
IBP(1,2) INIT ERR8			
IBP(1,2) COMM	IBP module failure	HIGH	Stop using the

STOP	or communication failure		measurement function of IBP module, notify biomedical engineer or Our service staff.
IBP(1,2) COMM ERR	IBP module failure or communication failure	HIGH	Stop using the measurement function of IBP module, notify biomedical engineer or Our service staff.
IBP1 ALM LMT ERR	Functional safety failure	HIGH	Stop using the measurement function of IBP module, notify biomedical engineer or Our service staff.
IBP2 ALM LMT ERR	Functional safety failure	HIGH	Stop using the measurement function of IBP module, notify biomedical engineer or Our service staff.

Prompt message:

Message	Cause	Alarm Level
IBP1 SYS EXCEED	Systolic measuring value of channel 1 is beyond measurement range.	HIGH
IBP1 DIA EXCEED	Diastolic measuring value of channel 1 is beyond measurement range.	HIGH
IBP1 MEAN EXCEED	Mean measuring value of channel 1 is beyond measurement range.	HIGH
IBP2 SYS EXCEED	Systolic measuring value of channel 2 is beyond measurement range.	HIGH
IBP2 DIA EXCEED	Diastolic measuring value of channel 2 is beyond measurement range.	HIGH
IBP2 MEAN EXCEED	Mean measuring value of channel 2 is beyond measurement range.	HIGH
IBP1 NEED ZERO-CAL	IBP1 is not performed the zero calibration.	LOW
IBP2 NEED ZERO-CAL	IBP2 is not performed the zero calibration.	LOW

## Chapter 16 CO<sub>2</sub> Measuring

### 16.1 Introduction

The device adopts infrared absorption technology to measure the CO<sub>2</sub> concentration in the patient's breathing airway. The principle is that the CO<sub>2</sub> molecules can absorb the infrared energy with specific wavelength, and the amount of energy absorbed is directly related to the CO<sub>2</sub> concentration. When the infrared light emitted by the infrared light source penetrates the CO<sub>2</sub> sample, part of the energy will be absorbed by the CO<sub>2</sub> in the gas. On the other side of the infrared light source, use a photodetector to measure the residual infrared light energy which will be converted into the electrical signal. Comparing and adjusting the electrical signal and infrared light energy to accurately reflect the CO<sub>2</sub> concentration in the gas sample.

#### CO<sub>2</sub> measurement methods:

##### 1. Mainstream

Install the CO<sub>2</sub> sensor to the airway joint of respiratory system connected to the patient directly.

##### 2. Sidestream

The respiratory gas in the patient's respiratory airway was sampled using a constant sampling flow rate and analyzed by a built-in CO<sub>2</sub> sensor.

#### CO<sub>2</sub> measurement can provide:

1. One-channel CO<sub>2</sub> waveform.
2. EtCO<sub>2</sub>: End Tidal carbon dioxide, CO<sub>2</sub> value measured in the end of respiratory phase
3. InsCO<sub>2</sub>: Inspired Minimum CO<sub>2</sub>
4. AwRR: Air Way Respiratory Rate, respiratory times per minute.

## 16.2 Safety information

---

### WARNING

- Don't use the device in the environment with flammable anesthetic gas.
  - The device can only be operated by personnel having taken professional training and familiar with this manual.
  - Notice and prevent the electrostatic discharge (ESD) and electromagnetic interference (EMI) with other instruments.
  - When placing sensor cables or tubes, avoid intertwining or squeezing each other.
  - When the CO<sub>2</sub> module is wet or condensed, do not use it.
  - Do not connect the exhaust pipe to the ventilation duct.
  - The device and its accessories are free of latex.
  - If the patient can not tolerate the sampling rate of 50 ml / min ± 10 ml / min, please stop using it.
- 

#### NOTE:

- When you do not use CO<sub>2</sub> monitoring function, it is suggested to set "WORK MODE" to "STANDBY".

## 16.3 Monitoring steps

### 16.3.1 Sensor zeroing

When you use a new airway joint, you must calibrate as the following procedures:

1. Connect the sensor to the CO<sub>2</sub> module.
2. Select the CO<sub>2</sub> parameter area, set the "WORK MODE" to "MEASUREMENT" in "CO<sub>2</sub> SETUP"→"OTHER SET", then the information "CO<sub>2</sub> SENSOR WARM UP" will display on the screen.
3. After warm up, install the sensor on a clean and dry air-way adapter. The

adapter should be connected to the atmosphere and isolated from all CO<sub>2</sub> sources, including ventilators, patient breathing and your own breathing.

4. Select "ZERO" in "CO<sub>2</sub> SETUP" interface, then the information "To initiate a CO<sub>2</sub> sensor zero" will display on the screen.
5. Typical zeroing time is 6~10 s, the prompt information will disappear after zeroing.

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#### WARNING

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- When calibrating the sensor during the measurement, please disconnect it from the patient's airway.
- 

#### NOTE:

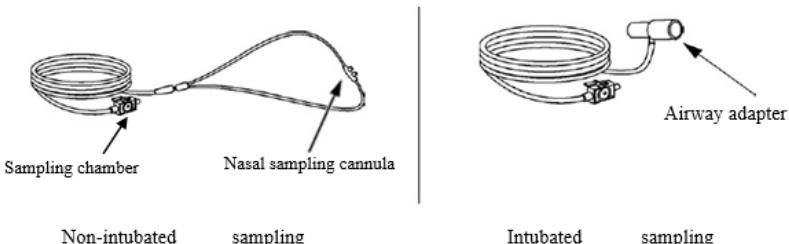
- When using a new airway adapter, it must be zeroed as described in this section.

### 16.3.2 Measurement setting for sidestream CO<sub>2</sub> module

#### 16.3.2.1 Measurement steps

1. Connect the sensor to the CO<sub>2</sub> module.
2. Set the "WORK MODE" to "MEASUREMENT" in "CO<sub>2</sub> SETUP"→"OTHER SET".
3. After start-up, the information "CO<sub>2</sub> SENSOR WARM UP" will display on the screen, the module locates in quasi-precision measurement state. Now the measurement can be performed, but the accuracy is low.
4. After warn up, the module will enter full-precision measurement state.

### Sidestream sampling cannula



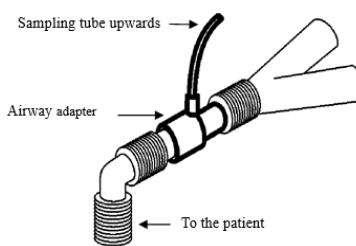
### Connection for sidestream and non-intubated patient



Wearing for Nasal

### Connection for sidestream and intubated patient

1. For the intubated patient, when using the airway adapter, install the adapter to the near-end of the loop, between the elbow bend and ventilator Y tube, as shown below.



- For intubated patients with an integrated airway respiration adapter in the breathing circuit: connect the luer male head on the sampling tube to the concave port of the airway adapter.



**NOTE:**

- Disconnect the cannula, airway adapter, or sampling tube from the sensor when it is not used.
- Before connecting the 3-way stopcock to the breathing circuit, make sure to properly connect the airway adapter and the sensor. Conversely, before removing the sensor, be sure to remove the airway adapter from the breathing circuit.
- Check the airway adapter before using it. If the airway adapter is already damaged or destroyed, do not use it.

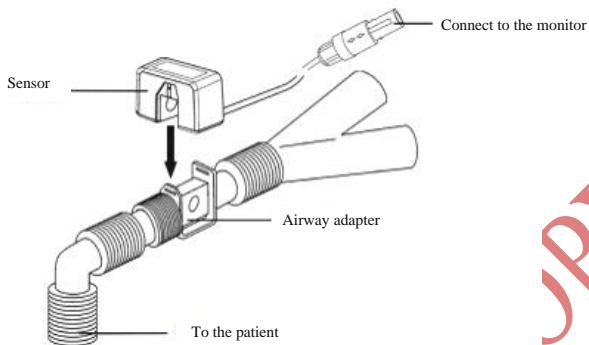
During measuring, if the tube falls off, it is necessary to re-calibrate after connecting well for further measurement.

#### **16.3.3 Measurement setting for mainstream CO<sub>2</sub> module**

**NOTE:**

- When using a new airway adapter, it must be zeroed as described in this section.
- Connect the sensor to the CO<sub>2</sub> module.
  - The information "CO<sub>2</sub> SENSOR WARM UP" will display on the screen.
  - After warm up, connect the sensor to the airway adapter.

4. Refer to relative chapter for zeroing the sensor.
5. After zeroing, connect the gas circuit as the following figure.



**NOTE:**

- Install the sensor above the adapter to prevent the liquid from gathering on the adapter window. The high concentration of liquid at this location will hinder the gas analysis.
- Use only sterile airway adapter or disposable airway adapter to avoid cross-contamination.
- Check the airway adapter before using it. If the airway adapter is already damaged or destroyed, do not use it.
- Regularly check flow sensor and sampling tube to prevent excessive moisture or secretions gathering.

#### 16.4 CO<sub>2</sub> Menu

Turn the knob to CO<sub>2</sub> hot key on the screen to activate "CO<sub>2</sub> Setup" menu as shown below:

- ALM REC: pick "ON", the system will output alarm information when CO<sub>2</sub> alarm occurs, the default is "OFF".
- SWEEP: adjust the display speed of CO<sub>2</sub> waveform, three options: "6.25

mm/s", "12.5 mm/s", or "25.0 mm/s".

- UNIT: change the display units of CO<sub>2</sub> and InsCO<sub>2</sub> parameters. Two options: "mmHg" and "kPa".
- CO<sub>2</sub> ALM SETUP:

Set the following contents after entering the initial password "70808":

- ◆ ALM: when CO<sub>2</sub> alarm occurs, the system will prompt and store the alarm information after selecting "ON", it will not alarm when selecting "OFF", and "" will appear in parameter area.
- ◆ ALM LEV: two options: HI and MED. "HI" is the most serious alarm, the second serious alarm is "MED". The change of "ALM LEV" only effects the physiological alarm level of CO<sub>2</sub> parameters(including EtCO<sub>2</sub> upper limit, EtCO<sub>2</sub> lower limit, InsCO<sub>2</sub> upper limit, AwRR upper limit and AwRR lower limit). The default level is "MED".
- ◆ CO<sub>2</sub> ALM HI: adjust the upper limit of EtCO<sub>2</sub> alarm. If the measurement value is higher than CO<sub>2</sub> upper alarm limit, the information "CO<sub>2</sub> TOO HIGH" appears on the screen. After the measurement value returns to the normal one, the information disappears.
- ◆ CO<sub>2</sub> ALM LO: adjust the lower limit of EtCO<sub>2</sub> alarm. If the measurement value is lower than CO<sub>2</sub> lower alarm limit, the information "CO<sub>2</sub> TOO LOW" appears on the screen. After the measurement value returns to the normal one, the information disappears.
- ◆ INS ALM HI: adjust the upper limit of InsCO<sub>2</sub> alarm. If the measurement value is higher than InsCO<sub>2</sub> upper alarm limit, the information "INS TOO HIGH" appears on the screen. After the measurement value returns to the normal one, the information disappears.

- ◆ AWRR ALM HI: adjust the upper limit of AwRR alarm. If the measurement value is higher than the upper alarm limit of AwRR, the information "AWRR TOO HIGH" appears on the screen. After the measurement value returns to the normal one, the information disappears.
- ◆ AWRR ALM LO: adjust the lower limit of AwRR alarm. If the measurement value is lower than the lower alarm limit of AwRR, the information "AWRR TOO LOW" appears on the screen. After the measurement value returns to the normal one, the information disappears.
- ◆ APNEA ALM: after selecting the alarm time for APNEA alarm(7 options: 10 s, 15 s, 20 s, 25 s, 30 s, 35 s, and 40 s), the information "CO<sub>2</sub> APNEA" will appear on the screen after the corresponding time selected. The alarm level is "HI".

OTHER SET: select it to enter "CO<sub>2</sub> SETUP" interface.

- WAVE SCALE: adjust the amplitude of CO<sub>2</sub> waveform display area, two options: "LO" or "HI", the default value is "LO".
- WORK MODE: change the work mode of CO<sub>2</sub>, two options: MEASUREMENT or STANDBY, the default is "STANDBY". When you need to perform CO<sub>2</sub> monitoring, select "MEASUREMENT".
- ATMOS (mmHg): adjust current atmospheric pressure, range: 400 mmHg~850 mmHg, Resolution: 1 mmHg, default:760 mmHg.
- O<sub>2</sub> COMPENSATE: set the gas compensation, which is used with "BALANCE GAS" and "ANEAL" together. Adjustable range: 0~100%, accuracy: 1%, default: 16%.
- BALANCE GAS: set the gas compensation, which is used with "O<sub>2</sub> COMPENSATE" and "ANEAL" together. Three options: room air, N<sub>2</sub>O and Helium. The default is "room air".

- ANEA: set the gas compensation, which is used with "O2 COMPENSATE" and "BALANCE GAS" together. Adjustable range: 0.0~20.0 %, accuracy: 0.1%, default: 0.0 %.

**NOTE:**

- Anesthetic gas will ignore it when the balance gas is set to "Helium".
- Zero: "Sample Cell Zero" is a quick process that allows the module to accommodate the optical characteristics of the different adapter types. "Sample Cell Zero" should be performed whenever the type of adapter being used with the module is changed. For optimal accuracy, "Sample Cell Zero" should also be performed whenever the module is connected to the host system.
- DEFAULT: select it to enter "CO<sub>2</sub> DEFAULT CONFIG" menu, in which the user may select "FACTORY DEFAULT CONFIG" or "USER DEFAULT CONFIG". After selecting one item and exiting the menu, the system will pop up the dialog box asking for your confirmation.

## 16.5 Influence factors

The following factors may affect the measurement accuracy:

- Leakage or internal leakage of sampling gas.
- Mechanical shock.
- Other interference sources of interference.

## 16.6 Alarm Information and Prompts

When the alarm switches are set to "ON" in relevant menus, the physiological alarms caused by the parameter exceeding the alarm limit may possibly trigger the recorder to automatically output the alarm parameter value and corresponding waveforms.

Tables below describe the possible physiological alarms, technical alarms and prompt messages occurring during CO<sub>2</sub> measurement.

Physiological alarms:

Message	Cause	Alarm Level
CO <sub>2</sub> HI	EtCO <sub>2</sub> measuring value is above upper alarm limit.	User-selectable
CO <sub>2</sub> LOW	EtCO <sub>2</sub> measuring value is below lower alarm limit.	User-selectable
INS HI	InsCO <sub>2</sub> measuring value is above alarm limits.	User-selectable
AWRR HI	AwRR measuring value is above upper alarm limit.	User-selectable
AWRR LOW	AwRR measuring value is below lower alarm limit.	User-selectable
CO <sub>2</sub> APNEA	RESP stops(in specific time interval, no RESP can be detected using CO <sub>2</sub> module.).	HIGH

Technical alarms:

Message	Cause	Alarm Level	Remedy
CO <sub>2</sub> SENSOR FAULT	The sensor error.	HIGH	Check that the sensor is properly plugged in. Reinsert or reset the sensor if necessary. If error persists, return sensor to factory for servicing.
CO <sub>2</sub> SENSOR	The sensor	HIGH	Make sure the sensor is not

OVER TEMP	temperature is greater than 40°C		exposed to extreme heat. If error persists, return sensor to factory for servicing.
CO <sub>2</sub> CHECK SAMPLING LINE	The atmospheric pressure exceeds the specified range.	LOW	Check whether the sampling cannula is occluded or twined.
CO <sub>2</sub> ZERO ERROR	An error was found during Zeroing	LOW	Check and clean the air adapter, if the error is not corrected, please calibrate zero.
CO <sub>2</sub> OUT OF RANGE	The value being calculated is greater than the upper CO <sub>2</sub> limit.	LOW	Calibrate zero.
CO <sub>2</sub> CHECK AIRWAY ADAPTER	It is usually caused when the airway adapter is removed from the sensor or when there is an optical blockage on the windows of the airway adapter. It may also be caused by performing false Zero When adapter type is changed.	LOW	If there is obvious sticky material or moisture on the air adapter, please clean it before calibrating zero.

CO <sub>2</sub> NOT INITIALIZED	Barometric Pressure or gas compensations have not been set after power on.	LOW	Set the Barometric Pressure and gas compensations to clear this error.
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Prompt message:

Message	Cause	Alarm Level
CO <sub>2</sub> ZERO IN PROGRESS	A Zero is currently in progress	No alarm
CO <sub>2</sub> SENSOR WARM UP	It shows that the sensor is in warming-up stage.	No alarm
CO <sub>2</sub> CHECK ADAPTER		No alarm
CO <sub>2</sub> ZERO REQUIRED		No alarm
CO <sub>2</sub> Sample Line Disconnected	This is no sidestream sampling set connected to the CO <sub>2</sub> sensor	No alarm

## Chapter 17 Battery

### 17.1 Introduction

The device can configure the rechargeable battery(lithium battery), which can ensure that the device can be used normally when the patient is moving in hospital or in the condition of power failure. The battery can be charged once connecting to the AC, no matter whether the the device is powered on. When sudden power interruption appears, the system will operate by the battery.

### 17.2 Battery status information

The battery status information displays the battery condition, which can be used to estimate the monitoring time.



The battery works normally, and the solid represents the battery power.



The battery power is low and low-battery alarm appears, it indicates that the battery needs to be charged immediately.



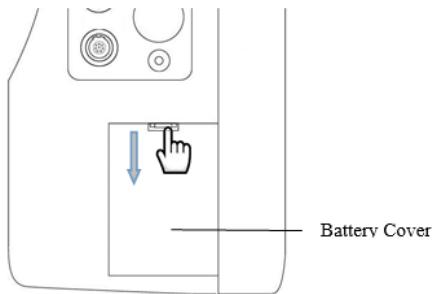
The battery is not installed.

Working by the battery can only maintain a period of time. Too low voltage will trigger high-level technical alarm "Low battery", then you should charge to the battery, otherwise it will shut down after the first alarm (about 5 minutes).

### 17.3 Battery installation

Refer to the following contents to install or replace the battery:

1. Open the battery compartment cover.



2. Move the push-button on the battery compartment toward to upper side to take the battery out.
3. Insert the new battery.
4. Move the push-button toward to below side to fix the battery, then install the battery compartment cover.

#### **17.4 Check for battery performance**

The battery performance may decrease with the increasing of use time. Please refer to the following steps to check the battery performance.

1. Disconnect the connection between the device and the patient to stop all monitoring and measurement.
2. Connect the device to AC to continuously charge the battery for above 10 hours.
3. Disconnect the AC, use the battery to supply power for the device till shutdown.
4. Battery-powered time reflects the battery performance.

If the battery-powered time is obviously lower than the time claimed in the Specification, please replace the battery or contact the service personnel.

---

## WARNING

- Please read the manual and safety information carefully before using the rechargeable lithium battery(hereinafter referred to as "battery").
- Keep the battery out of children's reaching.
- Don't take out the battery during monitoring.
- Don't connect the anode and cathode falsely to avoid explosive hazard.
- Don't heat the battery or throw it into the fire.
- Don't use the battery near the fire source or in the environment of temperature over +60°C.
- Don't throw the battery into the water, nor wet the battery.
- Don't destroy the battery: don't chisel the metal into the battery, or hammer or knock the battery, or use other methods to destroy the battery, to avoid the the battery heating, smoking, deformation or burning, even producing risks.
- Only the battery specified by the manufacturer can be used.
- The battery can only be used in the device. Necessary maintenance must be performed by qualified and trained service engineers ONLY.
- If the electrolyte exudes and enters your eye, please don't knead your eye, use clean water to rinse immediately and go to the doctor.
- If there is the sign of battery damage or leakage, please replace it immediately. Don't use the faulted battery.

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### NOTE:

- In order to protect the environment, please recycle the scrap battery as the regulations.
- When the device is turned off arisen from power failure, the system will save the latest settings before power failure when it is turned on again.

## **17.5 Battery maintenance**

The battery should be maintained periodically to prolong its use life, pay attention to the following instructions:

- During storing the battery, please charge to it once per 3 months at least.
- Battery performance must be checked once per 2 years. And it also should be checked when the device is maintained or you doubt the battery is the fault source.
- Please take out the battery before transporting the device or the device is not used over 3 months.
- If the device is not used for a long time, and the battery is not taken out, please charge to the battery once per 3 months, to avoid shortening the battery life.

## **17.6 Battery recycle**

The battery should be replaced and recycled properly if it has obvious damage or it can not store the power normally. The disposal of scrap battery should follow the relevant laws and regulations.

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### **WARNING**

- Don't disassembly the battery, or throw it into the fire, or make it short circuit. As battery burn, explosion or leakage may injury to the human.
-

## **Chapter 18 Maintenance and Cleaning**

Only use the material and method listed in this chapter to clean or maintain the device. Otherwise we do not provide any guarantee.

Our company has verified the cleaning and disinfection methods described in the manual. Professional personnel in hospital should obey the manual to ensure sufficient cleaning and disinfection.

### **18.1 Introduction**

Keep the device and accessories out of dust. In order to prevent damage, please obey the following rules:

- Please dilute the detergent and disinfectant according to the manufacturer's instructions, or adopt the lower concentration as soon as possible.
- Don't immerse the device into the liquid.
- Don't pour the liquid into the device or accessories.
- Don't allow liquid to enter into the enclosures.
- Don't use abrasion material(such as steel wool or silver polishing agent) and any strong solvent(such as acetone or the detergent contained acetone).

### **18.2 Cleaning**

The device should be cleaned periodically, in the area of seriously polluted or greater sand wind, cleaning frequency should be increased. Before cleaning, please consult or understand the regulations about device cleaning in advance.

Selectable detergents:

- Diluted ammonia water
- Diluted sodium hypochlorite(Bleaching powder).
- Hydrogen Peroxide(3%)

- Alcohol(70%)
- Isopropanol(70%)

When cleaning the device with the adsorption detergent, or wipe the residual detergent after cleaning, please use the clean and non-corrosive soft cloth or paper towel.

#### 18.2.1 Cleaning for host

Clean the device surface according to the following steps:

1. Turn off the power and unplug the power cord.
2. Use the soft cloth adsorbed proper detergent to completely wipe the external surface(including the LCD) of the device until that there is no obvious dirt.
3. After cleaning, please use the new cloth or paper towel adsorbed proper tap-water to wipe the residual detergent until that there is no obvious dirt.
3. Place the device in ventilation and shady environment for air drying.

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#### WARNING

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- Before cleaning, make sure that the device is switched off and disconnected from the power cord.
- 

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#### CAUTION

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- If the liquid is poured into the device or the accessories carelessly, please contact with our company or our service personnel immediately.
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## **18.2.2 Cleaning for the reusable accessories**

### **18.2.2.1 Cleaning for the ECG lead cables**

1. Use the soft cloth adsorbed proper detergent to completely wipe the lead cable surface until that there is no obvious dirt.
2. After cleaning, please use the new cloth or paper towel adsorbed proper tap-water to wipe the residual detergent until that there is no obvious dirt.
3. Use a dry soft to wipe the residual water.
4. Place the lead cable in ventilation and shady environment for air drying.

### **18.2.2.2 Cleaning for NIBP cuff**

Clean the cuff:

1. Take out the gasbag before cleaning.
2. The cuff should not be dry-cleaned, but it can be machine-washed or hand-washed, and the latter method may prolong the service life of the cuff. The cuff can be sterilized by means of conventional autoclaving, gas, or radiation sterilization in hot air ovens or disinfected by immersing in decontamination solutions, but remember to remove the gasbag if you use this method.
3. After cleaning, please use the new cloth or paper towel adsorbed proper tap-water to wipe the residual detergent until that there is no obvious dirt.
4. Use a dry soft to wipe the residual water.
5. Place the cuff in ventilation and shady environment for air drying.

Replace the gasbag:

After cleaning, install the gasbag into the cuff according to the following steps:

1. Roll up the gasbag lengthwise, place it into the cuff from the cuff side of the big opening.
2. Thread the leather hose of airbag from the small hole on the cuff, from inside to outside.

3. Adjust the gasbag location in cuff.

#### **18.2.2.3 Cleaning for SpO<sub>2</sub> probe**

1. Use the soft cloth adsorbed proper detergent to wipe the probe and lead cable surface until that there is no obvious dirt.
2. Use the cotton swab adsorbed proper detergent to completely wipe the contact position between the probe and the patient until that there is no obvious dirt.
3. After cleaning, please use the new cloth or paper towel adsorbed proper tap-water to wipe the residual detergent until that there is no obvious dirt.
4. Use a dry soft to wipe the residual water.
5. Place the probe in ventilation and shady environment for air drying.

#### **18.2.2.4 Cleaning for TEMP probe**

1. Use the soft cloth adsorbed proper detergent to wipe the contact position between the probe and the patient until that there is no obvious dirt.
2. After cleaning, please use the new cloth or paper towel adsorbed proper tap-water to wipe the residual detergent until that there is no obvious dirt.
3. Use a dry soft to wipe the residual water.
4. Place the probe in ventilation and shady environment for air drying.

#### **18.2.2.5 Cleaning for IBP cable**

1. Use the soft cloth adsorbed proper detergent to completely wipe the lead cable surface until that there is no obvious dirt.
2. After cleaning, please use the new cloth or paper towel adsorbed proper tap-water to wipe the residual detergent until that there is no obvious dirt.
3. Use a dry soft to wipe the residual water.
4. Place the cable in a ventilation and shady environment for air drying.

### **18.3 Disinfection**

To avoid extended damage to the device, disinfection is only recommended when stipulated as necessary in the Hospital Maintenance Schedule. The device should be cleaned firstly before disinfection.

Disinfectant recommended: alcohol(70%), isopropanol(70%).

If alcohol or isopropanol is used in both cleaning and disinfection, please clean cloth for disinfection.

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**WARNING**

- The hospital or medical institution using the device should establish a perfect maintenance plan, otherwise it may result in device failure and unpredictable consequences, even endanger personal safety.
  - All safety inspections or maintenance works to the components to be disassembled should be carried out by professional service personnel, otherwise it may result in device failure, even endanger personal safety.
  - If any problem has been found, please contact the service person or our company.
- 

### 19.1 Check

The device should be completely checked before using, or after continuous use of 6 to 12 months, maintenance or upgrading, to ensure normal operation and working.

The items to be checked should include:

- Environment and power meet the requirements.
- No abrasion and good insulation performance for the power cord.
- No mechanical damage for the device and accessories.
- The accessories specified are used.
- Alarm functions are normal.
- The recorder works normally, the recording paper conforms with specified requirements.
- Battery performance.
- Each monitoring function is in good working state.
- Ground impedance and leakage current conform requirements.

If any signs of damage to the instrument can be found, please don't use the monitor to perform any monitoring on the patient. And contact the medical engineer of the hospital or the maintenance engineer of the company.

All inspections that require to open the device must be carried out by qualified service personnel. Safety and maintenance inspections may also be carried out by personnel of the Company.

## 19.2 Troubleshooting

### ■ Power failure

Install the battery when using the device. As if the mains is disconnected, the device supplied power by the battery, which only sustains a period of time, and it will be automatically switched to mains when it is connected. A low battery voltage will trigger a high-tech alarm "Low battery", and it will shut down after the first alarm (about 5 minutes), then all trend data will be lost.

### ■ Troubleshooting

#### Other problems related to ECG measurement

Symptoms	Possible reasons and solutions
Noisy ECG signal or no QRS waveform is checked.	<ul style="list-style-type: none"><li>Make sure that the patient does not tremble.</li><li>Incorrect ECG filter.</li><li>The electrode is poor in quality or placed in a wrong position. Check the electrodes, cables and their placement. Refer to "ECG Monitoring" for details.</li><li>Replace a lead. Remove the ECG cable from the interface and insert it again.</li></ul>

Thick ECG baseline.	ECG cable is looped. Other power cables are close to ECG lead cables. Inappropriate power frequency.
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#### Other problems related to RESP measurement

Symptoms	Possible reasons and solutions
Failure in RESP measurement.	<ul style="list-style-type: none"> <li>Check electrode quality and placement.</li> <li>Other electrical equipment may interfere the measurement.</li> </ul>

#### Other problems related to NIBP measurement

Symptoms	Possible reasons and solutions
NIBP measurement can not be performed.	<ul style="list-style-type: none"> <li>Check whether the cuff is bent, stretched, squeezed, or loose.</li> <li>Use a cuff in proper size.</li> </ul>

#### Other problems related to TEMP measurement

Symptoms	Possible reasons and solutions
Failure in TEMP measurement.	<ul style="list-style-type: none"> <li>Check whether an appropriate probe is used.</li> <li>Try the other one.</li> </ul>

#### Other problems related to SpO<sub>2</sub> measurement

Symptoms	Possible reasons and solutions
The signal is weak.	<ul style="list-style-type: none"> <li>Check the probe and its placement.</li> <li>Note that skin pigmentation can cause deviations.</li> <li>Make sure the patient is not trembling.</li> </ul>

#### Other problems related to battery

Symptoms	Possible reasons and solutions
Battery working time significantly shortens.	<ul style="list-style-type: none"> <li>Maintain the battery according to the descriptions in the manual</li> </ul>

## Other conditions

Other possible conditions and reasons are listed in the table.

## Other operation problems

Symptoms	Possible reasons and solutions
The device can not print.	<ul style="list-style-type: none"><li>The battery power is low and the host is not connected to AC.</li></ul>
The measurement value does not display.	<ul style="list-style-type: none"><li>Check if you have selected the required parameters for the waveform or digital area.</li></ul>
The device can not turn on.	<ul style="list-style-type: none"><li>Check whether the power cord is connected correctly.</li><li>Check the fuses and replace them if necessary.</li></ul>
The screen stop in LOGO interface.	<ul style="list-style-type: none"><li>Replace the mainboard, or contact the engineer to re-brush the mainboard program.</li></ul>

## 19.3 Maintenance plan

The following tasks can only be performed by the professional maintenance staff authorized by our company. Please contact the service personnel when you need the following maintenance. Before test or maintenance, the device must be cleaned and disinfected.

Check/maintenance items	Frequency
Safety check according to IEC60601-1.	When replacing the power supply or after the device falls off.
NIBP air leakage check.	At least once per two years, or check according to the provisions of the hospital.

NIBP pressure check.	At least once per two years, or check according to the provisions of the hospital.
NIBP calibration.	At least once per two years, or check according to the provisions of the hospital.
TEMP calibration.	At least once per two years, or check according to the provisions of the hospital.

#### 19.4 NIBP CALIBRATE

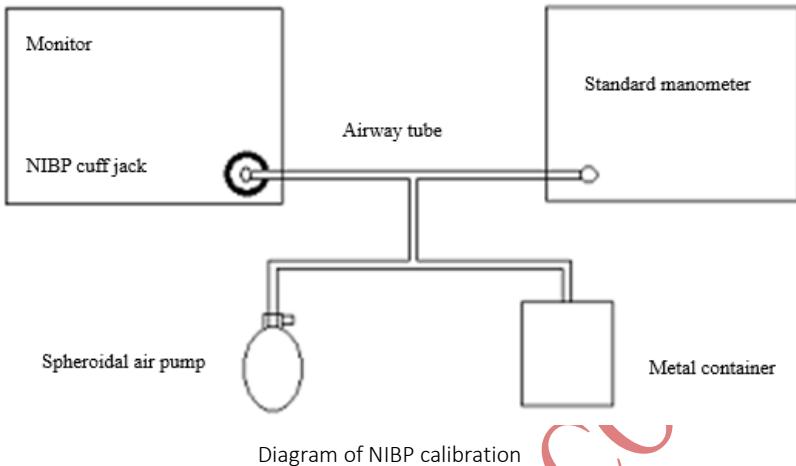
NIBP pressure calibration should be performed once per two years at least or once when you thought that the reading is inaccurate.

Prepared materials:

- Standard manometer
- Metal container (500 mL)
- Spheroidal air pump
- Airway tube
- T-shape connector

Procedures of the Pressure Transducer Calibration:

Replace the stuff with a metal container with a capacity of  $500\text{ mL} \pm 5\%$ . Connect a calibrated standard manometer, spheroidal air pump (error less than 0.8 mmHg), and airway tube to the NIBP cuff jack of the module by T-shape connector. Set the monitor in “CALIBRATE” mode. Inflate the pressure in the metal container to 0, 50, and 200 mmHg by spheroidal air pump separately. The difference between the indicated pressure of the standard manometer and the monitor will not exceed 3 mmHg. Otherwise, please contact our customer service.



## 19.5 ECG Calibration

The ECG signal may be inaccurate due to hardware or software problems when you use the monitor. The main manifestation is that the amplitude of waveform becomes larger or smaller. In this case, you need to calibrate the ECG.

- Select ECG Parameter Area
- Select “ECG SETUP” → “OTHER SETUP” → “ECG CAL”. A square wave signal will appear on the screen.
- Compare the amplitude of the square wave with the scale, generally the square wave should be flush with the top and bottom of the ruler, and the error range should be within 5%.
- After calibration, select “STOP ECG CAL”.

**WARNING**

- Use only the accessories specified in this chapter, as other accessories may damage the monitor or fail to meet the specifications stated in this manual.
- Disposable accessories can only be used once, repeated use may lead to performance degradation or cross infection.
- If you find any damage to the accessories packing or accessories, please do not use the accessories.

**20.1 ECG Accessories**

**ECG electrodes**

Accessory No.	Accessory name	Description	Remark
1.4.07.00002	ECG electrode, adult, one packet(20 pcs)	Disposable	/
1.4.07.00003	ECG electrode, child, one packet(20 pcs)		

**ECG cable**

Accessory No.	Accessory name	Description	Remark
2.3.04.00213	5-lead, American Standard, TPU, adult gold-plated button-type	Repeatable	/
2.3.04.00214	5-lead, European standard, TPU, adult gold-plated button-type		
2.3.04.00215	5-lead, American Standard, TPU, children's gold-plated clip-type		
2.3.04.00216	5-lead, European Standard, TPU,		

	children's gold-plated clip-type		
2.3.04.00227	3-lead, American Standard, PVC, children's gold-plated clip-type		
2.3.04.00228	3-lead, European Standard, PVC, children's gold-plated clip-type		
2.3.04.00244	5-lead, American Standard, anti-defibrillation, TPU, adult gold-plated button-type		

## 20.2 SpO<sub>2</sub> Accessories

SpO<sub>2</sub> probe

Accessory No.	Accessory name	Applicable Population	Description	Remark
2.3.08.00004	Adult fingertip SpO <sub>2</sub> probe(3m)	Adult(>40 Kg)	Repeatable	Integrated SpO <sub>2</sub> probe
2.3.08.00007	Children fingertip SpO <sub>2</sub> probe(3m)	Children(10~40 Kg)		
2.3.08.00020	Adult fingerstall SpO <sub>2</sub> probe(3m)	Adult(>40 Kg)		
2.3.08.00025	Adult fingertip SpO <sub>2</sub> probe(old version, 3m)	Adult(>40 Kg)		
2.3.08.00003	DB7 adult fingertip SpO <sub>2</sub> probe(1m)	Adult(>40 Kg)	Repeatable	Separated SpO <sub>2</sub> probe
2.3.08.00016	DB7 children fingertip SpO <sub>2</sub>	Children(10~40 Kg)		

	probe(1m)			
2.3.08.00017	DB7 adult fingerstall SpO <sub>2</sub> probe(1m)	Adult(>40 Kg)		
2.3.08.00029	DB7 bundled SpO <sub>2</sub> probe(1m)	Adult or children(> 10 Kg)		
2.3.09.00001	SpO <sub>2</sub> probe extension cable(2m)		Repeatable	Separated extension cable

### 20.3 NIBP Accessories

Airway tube

Accessory No.	Accessory name	Description	Remark
2.3.11.00007	NIBP extension tube, gray TPU, both sides with quick connector(female)	Repeatable	/

Cuff

Accessory No.	Accessory name	Description	Remark
2.3.11.00001	Neonatal cuff, repeatable	Limb perimeter(6~11 cm)	/
2.3.11.00002	Infants cuff, repeatable	Limb perimeter(10~19 cm)	
2.3.11.00003	Children cuff, repeatable	Limb perimeter(18~26 cm)	
2.3.11.00004	Adult cuff, repeatable	Limb perimeter(25~35 cm)	

2.3.11.00005	Adult cuff, repeatable, large size	Limb perimeter(33~47 cm)	
2.3.11.00006	Leg cuff for adult, repeatable	Limb perimeter(46~66 cm)	

#### 20.4 TEMP Accessories

TEMP probe

Accessory No.	Accessory name	Description	Remark
2.3.06.00001	Temperature probe( $R_{25} = 2.252K$ ), body surface type, PVC, L=3 m	Repeatable	/
2.3.06.00002	Temperature probe( $R_{25} = 2.252K$ ), body cavity type, PVC, L=3 m		
2.3.06.00017	Temperature probe( $R_{25} = 2.252K$ ), body surface type, TPU, L=3 m		
2.3.06.00018	Temperature probe( $R_{25} = 2.252K$ ), body cavity type, TPU, L=3 m		

#### 20.5 IBP accessories

Accessory No.	Accessory name	Description	Remark
2.3.02.00001	IBP integrated module/IBP-100	/	Ancillary use
2.3.07.00026	IBP cable/DGT0026	Reusable	
1.4.11.00007	IBP sensor/PT-01	Disposable	

## 20.6 CO<sub>2</sub> Accessories

Sidestream module

Accessory No.	Accessory name	Description	Remark
2.3.02.00068	CO <sub>2</sub> module/CO <sub>2</sub> -M01, sidestream, green	/	/
2.3.02.00069	CO <sub>2</sub> module/import sidestream(1022054), green	/	/

Sampling cannula and adapter

1.4.11.00032	Adult nasal sampling cannula with drying tube / DM-4100-AMLT	Disposable	Only for CO <sub>2</sub> -M01, sidestream module
1.4.11.00033	Sampling cannula with drying tube, intubation patient /DM-7700-MLT		
1.4.11.00026	Neonatal nasal sampling cannula / DM-3500		
1.4.11.00006	Adult nasal sampling cannula kit/3468ADU-00	Disposable	Only for import sidestream module
1.4.11.00013	Child/adult airway adapter /3472ADU-00		
1.4.11.00014	Child/adult airway adapter with dehumidification tubing / 3473ADU-00		
1.4.11.00015	Extension tube(with drying tube)/ 3475-00		
1.4.11.00021	Child nasal sampling cannula kit/3468PED-00		

1.4.11.00022	Infant nasal sampling cannula kit/3468INF-00		
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Mainstream module

Accessory No.	Accessory name	Description	Remark
2.3.02.00031	CO <sub>2</sub> module/CO <sub>2</sub> -M02, mainstream	/	/
2.3.02.00070	CO <sub>2</sub> module/import mainstream(1015928), green		
<b>Airway adapter</b>			
1.4.11.00019	Adult/child airway adapter/P/N-6063-00	Disposable	Mainstream
1.4.11.00020	Infant/neonatal airway adapter/ P/N-6312-00		

## Chapter 21 Default Settings

This appendix documents the most important default settings of your monitor as it is delivered from the factory. For a comprehensive list and explanation of default settings, see the Configuration Guide supplied with your monitor. The monitor's default settings can be permanently changed in Configuration Mode.

### NOTE:

- If your monitor has been ordered preconfigured to your requirements, the settings at delivery will be different from those listed here.

### 21.1 Country-Specific Default Settings

Certain default settings are specific to a particular country. These are listed here for all countries alphabetically.

Country-Description	Line Frequency	Units Weight	Units Height	ECG	Cable Color
	50/60 [Hz]	kg, lb	in, cm	IEC, AAMI	
Afghanistan	50	kg	cm	AAMI	
Åland Islands	50	kg	cm	IEC	
Albania	50	kg	cm	IEC	
Algeria	50	kg	cm	IEC	
American Samoa	60	lb	in	AAMI	
Andorra	60	lb	in	AAMI	
Angola	50	kg	cm	IEC	
Anguilla	60	lb	in	AAMI	
Antarctica	60	lb	in	AAMI	
Antigua and Barbuda	50	kg	cm	AAMI	
Argentina	50	kg	cm	AAMI	

Armenia	50	kg	cm	IEC
Aruba	60	kg	cm	AAMI
Australia	50	kg	cm	AAMI
Austria	50	kg	cm	IEC
Azerbaijan	50	kg	cm	IEC
Bahamas, The	60	kg	cm	AAMI
Bahrain	50	kg	cm	AAMI
Bangladesh	60	lb	in	AAMI
Barbados	50	kg	cm	AAMI
Belarus	50	kg	cm	IEC
Belgium	50	kg	cm	IEC
Belize	60	lb	in	AAMI
Benin	60	lb	in	AAMI
Bermuda	60	kg	cm	AAMI
Bhutan	60	lb	in	AAMI
Bolivia	50	kg	cm	AAMI
Bosnia and Herzegovina	50	kg	cm	IEC
Botswana	50	kg	cm	IEC
Bouvet Island	60	lb	in	AAMI
Brazil	60	kg	cm	AAMI
British Indian Ocean Territory	60	lb	in	AAMI
Brunei Darussalam	50	kg	cm	AAMI
Brunei	50	kg	cm	IEC
Bulgaria	50	kg	cm	IEC
Burkina Faso	50	kg	cm	IEC
Burundi	50	kg	cm	IEC

Cambodia	50	kg	cm	IEC
Cameroon	50	kg	cm	IEC
Canada	60	kg	cm	AAMI
Cape Verde	60	lb	in	AAMI
Cayman Islands	60	kg	cm	AAMI
Central African Republic	50	kg	cm	IEC
Chad	60	lb	in	AAMI
Chile	50	kg	cm	AAMI
China	50	kg	cm	IEC
Christmas Islands	60	lb	in	AAMI
Cocos Keeling Islands	60	lb	in	AAMI
Colombia	60	kg	cm	AAMI
Comoros	60	lb	in	AAMI
Congo	50	kg	cm	IEC
Congo, Democratic Republic of the	50	kg	cm	IEC
Cook Islands	60	lb	in	AAMI
Costa Rica	60	kg	cm	AAMI
Côte d'Ivoire	50	kg	cm	IEC
Croatia	50	kg	cm	IEC
Cuba	60	kg	cm	IEC
Cyprus	50	kg	cm	IEC
Czech Republic	50	kg	cm	IEC
Denmark	60	lb	in	AAMI
Djibouti	50	kg	cm	IEC
Dominica	50	kg	cm	AAMI

Dominican Republic	60	kg	cm	AAMI
Ecuador	60	kg	cm	AAMI
Egypt	50	kg	cm	IEC
El Salvador	60	kg	cm	AAMI
Equatorial Guinea	50	kg	cm	IEC
Eritrea	50	kg	cm	IEC
Estonia	50	kg	cm	IEC
Ethiopia	50	kg	cm	IEC
Falkland Islands, Malvinas	60	lb	in	AAMI
Faroe Islands	60	lb	in	AAMI
Fiji	60	lb	in	AAMI
Finland	50	kg	cm	IEC
France	50	kg	cm	IEC
French Guiana	50	kg	cm	IEC
French Polynesia	60	lb	in	AAMI
French Southern Territories	60	lb	in	AAMI
Gabon	50	kg	cm	IEC
Gambia, The	50	kg	cm	IEC
Georgia	60	lb	in	AAMI
Germany	50	kg	cm	IEC
Ghana	50	kg	cm	IEC
Gibraltar	60	lb	in	AAMI
Greece	50	kg	cm	IEC
Greenland	60	lb	in	AAMI
Grenada	50	kg	cm	AAMI
Guadeloupe	50	kg	cm	IEC

Guam	60	lb	in	AAMI
Guatemala	60	kg	cm	AAMI
Guernsey	50	kg	cm	IEC
Guinea	60	lb	in	AAMI
Guinea-Bissau	60	lb	in	AAMI
Guyana	60	kg	cm	AAMI
Haiti	60	kg	cm	AAMI
Heard Island and McDonald Islands	60	lb	in	AAMI
Holy See, Vatican City State	60	lb	in	AAMI
Honduras	60	kg	cm	AAMI
Hong Kong	50	kg	cm	IEC
Hungary	50	kg	cm	IEC
Iceland	50	kg	cm	IEC
India	50	kg	cm	IEC
Indonesia	50	kg	cm	IEC
Iran, Islamic Republic of	50	kg	cm	AAMI
Iraq	50	kg	cm	AAMI
Ireland	50	kg	cm	IEC
Isle of Man	50	kg	cm	IEC
Israel	50	kg	cm	IEC
Italy	50	kg	cm	IEC
Jamaica	50	kg	cm	AAMI
Japan	60	kg	cm	IEC
Jersey	50	kg	cm	IEC
Jordan	50	kg	cm	AAMI

Kazakhstan	50	kg	cm	IEC
Kenya	50	kg	cm	IEC
Kiribati	60	lb	in	AAMI
Korea, Democratic People's Republic of	60	lb	in	AAMI
Korea, Republic of	60	kg	cm	AAMI
Kuwait	50	kg	cm	AAMI
Kyrgyzstan	60	lb	in	AAMI
Lao People's Democratic Republics	50	kg	cm	IEC
Latvia	50	kg	cm	IEC
Lebanon	50	kg	cm	AAMI
Lesotho	50	kg	cm	IEC
Liberia	50	kg	cm	IEC
Libyan Arab. Jamahiriya	60	lb	in	AAMI
Liechtenstein	60	lb	in	AAMI
Lithuania	50	kg	cm	IEC
Luxembourg	50	kg	cm	IEC
Macao	60	lb	in	AAMI
Macedonia, The former Yugoslav. Rep. of	50	kg	cm	IEC
Madagascar	50	kg	cm	IEC
Malawi	50	kg	cm	IEC
Malaysia	50	kg	cm	IEC
Maldives	60	lb	in	AAMI
Mali	50	kg	cm	IEC

Malta	50	kg	cm	IEC
Marshall Islands	60	lb	in	AAMI
Martinique	60	kg	cm	IEC
Mauritania	50	kg	cm	IEC
Mauritius	60	lb	in	AAMI
Mayotte	60	lb	in	AAMI
Mexico	60	kg	cm	AAMI
Micronesia, Fed. States of	60	lb	in	AAMI
Moldova, Republic of	60	lb	in	AAMI
Monaco	60	lb	in	AAMI
Mongolia	60	lb	in	AAMI
Montenegro	50	kg	cm	IEC
Montserrat	50	kg	cm	AAMI
Morocco	50	kg	cm	IEC
Mozambique	50	kg	cm	IEC
Myanmar	60	lb	in	AAMI
Namibia	50	kg	cm	IEC
Nauru	60	lb	in	AAMI
Nepal	60	lb	in	AAMI
Netherlands	50	kg	cm	IEC
Netherlands Antilles	50	kg	cm	AAMI
New Caledonia	60	lb	in	AAMI
New Zealand	50	kg	cm	AAMI
Nicaragua	60	kg	in	AAMI
Niger	50	kg	cm	IEC
Nigeria	50	kg	cm	IEC

Niue	60	lb	in	AAMI
Norfolk Islands	60	lb	in	AAMI
Northern Mariana Islands	60	lb	in	AAMI
Norway	50	kg	cm	IEC
Oman	50	kg	cm	AAMI
Pakistan	50	kg	cm	IEC
Palau	60	lb	in	AAMI
Palestinian Territory	50	kg	cm	AAMI
Panama	60	lb	in	AAMI
Papua New Guinea	60	lb	in	AAMI
Paraguay	50	kg	cm	AAMI
Peru	60	kg	cm	AAMI
Philippines	60	kg	cm	AAMI
Pitcairn	60	lb	in	AAMI
Poland	50	kg	cm	IEC
Portugal	50	kg	cm	IEC
Puerto Rico	60	lb	in	AAMI
Qatar	50	kg	cm	AAMI
Reunion	60	lb	in	AAMI
Romania	50	kg	cm	IEC
Russian Federation	50	kg	cm	IEC
Rwanda	50	kg	cm	IEC
Saint Helena	60	lb	in	AAMI
Saint Kitts and Nevis	60	kg	cm	AAMI
Saint Lucia	50	kg	cm	AAMI
Saint Pierre and Miquelon	60	lb	in	AAMI

Saint Vincent and the Grenadines	50	kg	cm	AAMI
Samoa	60	lb	in	AAMI
San Marino	60	lb	in	AAMI
Sao Tome and Principe	60	lb	in	AAMI
Saudi Arabia	50	kg	cm	AAMI
Senegal	50	kg	cm	IEC
Serbia	50	kg	cm	IEC
Serbia & Montenegro	50	kg	cm	IEC
Seychelles	60	lb	in	AAMI
Sierra Leone	50	kg	cm	IEC
Singapore	50	kg	cm	IEC
Slovakia	50	kg	cm	IEC
Slovenia	50	kg	cm	IEC
Solomon Islands	60	lb	in	AAMI
Somalia	50	kg	cm	IEC
South Africa	50	kg	cm	IEC
South Georgia and the South Sandwich Islands	60	lb	in	AAMI
Spain	50	kg	cm	IEC
Sri Lanka	60	lb	in	AAMI
Sudan	50	kg	cm	IEC
Suriname	60	kg	cm	AAMI
Svalbard and Jan Mayen	60	lb	in	AAMI
Swaziland	60	lb	in	AAMI
Sweden	50	kg	cm	IEC

Switzerland	50	kg	cm	IEC
Syrian Arab Rep	50	kg	cm	AAMI
Taiwan, Province of China	60	kg	cm	AAMI
Tajikistan	60	lb	in	AAMI
Tanzania, United Republic of	60	lb	in	AAMI
Thailand	50	kg	cm	AAMI
Timor-Leste	60	lb	in	AAMI
Togo	60	lb	in	AAMI
Tokelau	60	lb	in	AAMI
Tonga	60	lb	in	AAMI
Trinidad and Tobago	60	lb	in	AAMI
Tunisia	50	kg	cm	IEC
Turkey	50	kg	cm	IEC
Turkmenistan	60	lb	in	AAMI
Turks and Caicos Islands	60	kg	cm	AAMI
Tuvalu	60	lb	in	AAMI
Uganda	60	lb	in	AAMI
Ukraine	60	lb	in	AAMI
UK	50	kg	cm	IEC
United Arab Emirates	50	kg	cm	AAMI
United Kingdom	50	kg	cm	IEC
United States	60	lb	in	AAMI
United States Minor Outlying Islands	60	lb	in	AAMI
Uruguay	50	kg	cm	AAMI
Uzbekistan	60	lb	in	AAMI

Vanuatu	60	lb	in	AAMI
Venezuela	60	lb	in	AAMI
Viet Nam	50	kg	cm	IEC
Virgin Islands (British)	50	kg	cm	AAMI
Virgin Islands (US)	60	lb	in	AAMI
Wallis and Futuna Islands	60	lb	in	AAMI
Western Sahara	50	kg	cm	IEC
Yemen	50	kg	cm	AAMI
Zambia	60	lb	in	AAMI
Zimbabwe	60	lb	in	AAMI

## 21.2 Alarm and Measurement Default Settings

Settings are only entered once per table row if they are the same for all patient categories.

### 21.2.1 Alarm

Name	Factory Default
ALARM VOL	1
ALM REC TIME	32 s
ALM PAUSE TIME	2 min
ALM TYPE	UNLATCH
KEYVOL	1
ALM SOUND	ON

### 21.2.2 ECG

Name	Factory Default		
	Adult	Pedi	Neo

FILTER	Monitor		
HR ALM	ON		
ALM LEV	MED		
ALM REC	OFF		
ALM HI	120 bpm	160 bpm	200 bpm
ALM LO	50 bpm	75 bpm	100 bpm
HR FROM	AUTO		
HR CHANNEL	CH1		
LEAD TYPE	5 LEAD		
SWEET	25.0 mm/s		

Arrhythmia analysis

Name	Factory Default		
	Adult	Pedi	Neo
ARR ANAL	OFF		
PVCS ALM	OFF		
ALM LEV	MED		
ALM REC	OFF		
ALM HI	10		

ST-segment analysis

Name	Factory Default		
	Adult	Pedi	Neo
ST ANAL	OFF		
ST ALM	OFF		

ST ALM LEV	MED
ST ALM SEC	OFF
ST ALM HI	0.20
ST ALM LO	-0.20

#### 21.2.3 RESP

Name	Factory Default		
	Adult	Pedi	Neo
ALM	ON		
ALM LEV	MED		
ALM REC	OFF		
ALM HI	30 rpm	100 rpm	
ALM LO	8 rpm	30 rpm	
SWEET	25 mm/s		
APENA ALM	20 s		
WAVE AMP	X1		
RESP FROM	LL-RA		

#### 21.2.4 SpO<sub>2</sub>

Name	Factory Default		
	Adult	Pedi	Neo
SpO <sub>2</sub> ALM	ON		
ALM LEV	Hi		
ALM REC	OFF		
SpO <sub>2</sub> ALM HI	100	100	95
SpO <sub>2</sub> ALM LOW	90	90	90
SWEET	25 mm/s		

PR ALM	ON		
PR ALM HI	120 bpm	160 bpm	200 bpm
PR ALM LO	50 bpm	75 bpm	100 bpm

#### 21.2.5 NIBP

Name	Factory Default		
	Adult	Pedi	Neo
ALM	ON		
ALM LEV	MED		
ALM REC	OFF		
SYS ALM HI	160 mmHg	120 mmHg	90 mmHg
SYS ALM LO	90 mmHg	70 mmHg	40 mmHg
MEAN ALM HI	110 mmHg	90 mmHg	70 mmHg
MEAN ALM LO	60 mmHg	50 mmHg	25 mmHg
DIA ALM HI	90 mmHg	70 mmHg	60 mmHg
DIA ALM LO	50 mmHg	40 mmHg	20 mmHg
UNIT	mmHg		
INTERVAL	MANUAL		
INFLATION	150 mmHg	100 mmHg	70 mmHg

#### 21.2.6 TEMP

Name	Factory Default		
	Adult	Pedi	Neo
ALM	ON		
ALM LEV	MED		
ALM REC	OFF		
T1 HI	39.0		

T1 LO	36.0
T2 HI	39.0
T2 LO	36.0
TD HI	2.0
UNIT	°C

#### 21.2.7 IBP

Name	Factory Default			
	Adult	Pedi	Neo	
ALM	ON			
ALM LEV	MED			
ALM REC	OFF			
SWEET	25.0 mm/s			
IBP1 UNIT	mmHg			
IBP2 UNIT	mmHg			
FILTER	No filter			
Alarm limit	Systolic/diastolic(mean) pressure(mmHg)			
	Adult	Pedi	Neo	
ART、P1、 P2 PA	ALM HI LM LO ALM HI LM LO	160/90(110) 90/50(70) 35/16(20) 10/0(0)	120/70(90) 70/40(50) 60/4(26) 24/-4(12)	90/60(70) 55/20(35) 60/4(26) 24/-4(12)
Alarm limit		Adult	Pedi	Neo
CVP、RAP、 LAP、ICP	ALM HI	10	4	4
	LM LO	0	0	0

#### 21.2.8 CO<sub>2</sub>

Name	Factory Default		
	Adult	Pedi	Neo
ALM	ON		
ALM LEV	MED		
ALM REC	OFF		
CO <sub>2</sub> ALM HI	45		
CO <sub>2</sub> ALM LO	30		
NS ALM HI	4		
AWRR ALM HI	30	30	100
AWRR ALM LO	8	8	30
APNEA ALM	20 s		
SWEET	25.0 mm/s		
Unit	mmHg		
WAVE SCALE	LOW		
WORK MODE	Standby		
ATMOS(mmHg)	760		
O2 COMPENSATE	16		
BALANCE GAS	Air		
ANEA	0.0		

## Appendix A Product Specification

### A.1 Classification

Anti-electroshock type	Class I, internal and external powered equipment
Anti-electroshock degree	Type CF defibrillation-proof applied part
Harmful liquid proof degree	IPX0 (protected against harmful effects of 15° tilted falling water drops)
Working mode	Continuous working

### A.2 Physical characteristic

Device	Dimension(L×W×H)	Weight
Device 1	319 mm × 161 mm × 269 mm	<3.0 kg (standard configuration, excluding accessories)
Device 2	314 mm × 145 mm × 264 mm	<3.0 kg (standard configuration, excluding accessories)
Device 3	319 mm × 167 mm × 268 mm	<3.0 kg (standard configuration, excluding accessories)

### A.3 Working environment

If used or stored outside the specified temperature and humidity range, the device may not meet the performance specifications listed here.

Working environment	
Temperature	+5 ~ +40 °C
Humidity	15 ~ 85 % RH

Atmospheric pressure	700 ~ 1060 hPa
<b>Storage environment</b>	
Temperature	-20 ~ +55 °C
Humidity	≤95% RH (no coagulation)
Atmospheric pressure	500 ~ 1060 hPa

#### A.4 Power supply

Input voltage	AC~ 100-240 V
Frequency	50/60 Hz
Input power	≤150 VA
Fuse	FUSE T1.6AL250V
Internal battery	
Battery type	Li-ion battery
Battery voltage	7.4 VDC
Battery capacity	5000 mAh
Minimum power supply time	180 min  Working conditions: use a new fully charged battery, ambient temperature: 25 °C.  Device configuration: continuous measurement for ECG and SpO <sub>2</sub> ; NIBP measurement in AUTO mode, measurement interval: 15 minutes
Charging time	90%: about 4 hours, fully charged: 5 hours

#### A.5 Display

Dimension(diagonal)	12.1 inch, color TFT display
Resolution	800×600
Display information	Up to 8-channel waveform

#### A.6 LED on host

Alarm indicator	One alarm indicator(yellow/red)
Battery indicator	One
AC power indicator	One

#### A.7 Recorder

Recorder type	Thermal dot-matrix
Waveform	2-channel
Recording width	48 mm
Paper length	20 m
Paper speed	25 mm/s, 50 mm/s
Recording type	Continuous real-time recording 8-second real-time recording Auto 8-second recording Parameter alarm recording Waveform freeze recording Trend graph/table recording ARR events review recording Alarm event review recording NIBP review recording SD card review recording

	Drug calculation and titration table recording
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#### A.8 Data storage

Trend recall	Short: 1 hour, resolution: 1 second Long: 480 hours, resolution: 1 minute
Alarm event recall	Physiological alarm: review for 72 alarm events of all parameters and 8/16/32-second of corresponding waveform. Technical alarm: 500 technical alarm events
Arrhythmia alarm event review	Review for 60 arrhythmia alarm events and 8-second of corresponding waveform.
NIBP measurement review	Review for the latest 4800 groups of NIBP data
SD card review	Trend data review: resolution: 1 minute 72-hour ECG waveform

#### A.9 ECG

Lead mode	3-lead: I, II, III 5-lead: I, II, III, aVR, aVL, aVF, V
Waveform	3-lead: 1-channel waveform 5-lead: 2-channel waveform, up to 7-channel waveform can be displayed on one display.
Lead style	AHA(American standard), IEC(European standard)
Sensitivity	2.5 mm/mV(x0.25), 5 mm/mV(x0.5), 10 mm/mV(x1), 20 mm/mV(x2), 40 mm/mV(x4)

Scan speed	12.5 mm/s, 25 mm/s, 50 mm/s
Frequency response(bandwidth)	Diagnosis: 0.05~75 Hz(+0.4 dB, -3 dB); 76~150 Hz(+0.4 dB,-4.5 dB) Monitoring: 0.67~40 Hz(+0.4 dB, -3 dB) Surgery: 1~20 Hz(+0.4 dB, -3 dB)
CMRR	Monitoring: ≥100 dB Surgery: ≥100 dB Diagnosis: ≥90 dB
NOTCH	50/60 Hz(NOTCH filter can be turned on or off manually)
Electrode polarization voltage range	± 500 mV
Lead-off check	DC for active lead: ≤0.1 μA (Drive lead≤1 μA)
Baseline recovery time	After defibrillation ≤5 s(under monitoring and surgery)
Calibration signal	1 mV(peak-to-peak value), accuracy: ±5 %
<b>Pacing pulse</b>	
Pulse display	II lead
Pulse indicator	Pulse is marked if the requirements of ANSI/AAMI EC13:2002, Sect. 4.1.4.1 are met: Amplitude: ±2~±700 mV Width: 0.1~2 ms Rise time: 10~100 μs
Pulse Rejection	Pulse is rejected if the requirements of ANSI/AAMI EC13-2002: Sect. 4.1.4.1 are met: Amplitude: ±2~±700 mV

	Width: 0.1~2 ms Rise time: 10~100 $\mu$ s	
Minimum input slew rate	> 3.5 V/s RTI	
Alarm limit	Range (bpm)	Step (bpm)
HR high limit	Adult: (low limit+1)~300 Pediatric and neonate: (low limit+1)~350	1
HR low limit	15~(high limit-1)	
<b>HR</b>		
Measurement limit	Adult: 15 ~ 300 bpm Pediatric and neonate: 15~350 bpm	
Accuracy	$\pm 1\%$ or $\pm 1$ bpm, whichever is greater	
Resolution	1 bpm	
Alarm accuracy	$\pm 2$ bpm	
Maximum suppression ability for T wave	1.2 mV	
HR mean	In the RR interval within the latest 6 seconds, take the average value after removing the maximum and minimum values.  The heart rate displayed on the screen is refreshed in every second.	
Response time for heart rate meter to HR change	80 to 120 bpm: < 8 s 80 to 40 bpm: < 8 s	

Heart rate meter accuracy and response to irregular rhythm	After stable phase(20s), the HR values are: Bigeminy ventricular: 80 bpm±1 bpm Bigeminy ventricular alternative lente: 60 bpm±1 bpm Bigeminy ventricular alternative rapid: 120 bpm ±1 bpm Systoles bidirectional: 95 bpm±1 bpm
Time to ALARM for tachycardia	
Tachycardia ventricular: amplitude =1 mV(p-v), heart rate =206 bpm	Gain 1.0: 8 s Gain 0.5: 8 s Gain 2.0: 8 s
Tachycardia ventricular : amplitude =2 mV(p-v), heart rate =195 bpm	Gain 1.0: 8 s Gain 0.5: 8 s Gain 2.0: 8 s
Arrhythmia type	ASYSTOLE, BIGEMINY, VFIB/VTAC, TRIGEMINY, PVC, R ON T, COUPLET, MISSED BEATS, VT>2, PNC, TACHY, PNP, BRADY
<b>ST-segment measurement</b>	
Measurement range	-2.0 mV~+2.0 mV
Accuracy	-0.8 mV~+0.8 mV: ±0.04 mV or ±10 %, whichever is greater. Other range: unspecified

### A.10 RESP

Measurement method	Impedance	
Waveform gain	2.5 mm/mV(x0.25),5 mm/mV(x0.5),10 mm/mV(x1),20 mm/mV(x2), 40 mm/mv(x4)	
Measurement impedance range	0.3 ~ 5 Ω	
Base line impedance range	500 ~ 2500 Ω	
Differential input impedance	> 2.5 MΩ	
Bandwidth	0.2 ~ 2.5 Hz	
Scan speed	6.25 mm/s, 12.5 mm/s, 25 mm/s	
RR		
Measurement range	0 ~ 150 rpm	
Resolution	1 rpm	
Accuracy	±2 rpm	
Apnea alarm	10~40 s	
Alarm limit	range (rpm)	Step (rpm)
Alarm high limit	(low limit+1)~150	1
Alarm low limit	Adult: 0~(high limit-1) Pediatric and neonate: 0~(high limit-1)	

### A.11 NIBP

Measurement method	Oscillometric		
Working mode	Manual, Auto, STAT		
Measurement Interval in AUTO Mode	1, 2, 3, 4, 5, 10, 15, 30, 60, 90, 120, 240, 480, 960 min		
Measuring Period in STAT Mode	5 min		
Measurement parameters	SYS, DIA, MEAN		
NIBP measurement range		Adult	Pediatric
	Systolic pressure (mmHg)	30 ~ 270	30 ~ 235
	Systolic pressure (kPa)	4 ~ 36.0	4 ~ 31.3
	Diastolic pressure (mmHg)	10~220	10~195
	Diastolic pressure (kPa)	1.3~29.3	1.3~26.0
	Mean pressure	20~235	20~210

	(mmHg)				
	Mean pressure (kPa)	2.7~31.3	2.7~28.0	2.7~14.7	
Accuracy	Maximum mean error: $\pm 5$ mmHg Maximum Standard deviation: 8 mmHg				
Pressure resolution	1 mmHg				
Cuff pressure accuracy	$\pm 3$ mmHg				
Over-pressure protection	Adult: $297 \text{ mmHg} \pm 3 \text{ mmHg}$ Pediatric: $240 \text{ mmHg} \pm 3 \text{ mmHg}$ Neonate: $147 \text{ mmHg} \pm 3 \text{ mmHg}$				
Alarm limit	Range (mmHg)	Step (mmHg)			
High limit of systolic pressure	Adult: $(\text{low limit}+1) \sim 270$ Pediatric: $(\text{low limit}+1) \sim 235$ Neonate: $(\text{low limit}+1) \sim 135$			1	
Low limit of systolic pressure	30~(high limit-1)				
High limit of diastolic pressure	Adult: $(\text{low limit}+1) \sim 220$ Pediatric: $(\text{low limit}+1) \sim 195$ Neonate: $(\text{low limit}+1) \sim 100$				
Low limit of diastolic pressure	10~(high limit-1)				
High limit of mean pressure	Adult: $(\text{low limit}+1) \sim 235$ Pediatric: $(\text{low limit}+1) \sim 210$ Neonate: $(\text{low limit}+1) \sim 110$				

Low limit of mean pressure	20~(high limit-1)	
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#### A.12 SpO<sub>2</sub>

Note : The claims of SpO<sub>2</sub> accuracy shall be supported by clinical study measurements taken over the full range. By artificially inducing to different oxygen levels, in the range of 70% to 100% SaO<sub>2</sub>, compare the SpO<sub>2</sub> values collected by the secondary standard pulse oximeter equipment and the tested equipment at the same time to form data pairs, which are used as an accuracy analysis. Because pulse oximeter equipment measurements are statistically distributed, only about two-thirds of pulse oximeter equipment measurements can be expected to fall within  $\pm$ Arms of the value measured by a CO-OXIMETER.

Measurement and display range	0 ~ 100 %		
Resolution	1 %		
Accuracy	70 ~ 100 %: $\pm$ 2 %; 0 ~ 69 %: unspecified;		
Updating cycle	About 1 s		
Mean time	4 s, 8 s, 16 s		
Alarm limit	Range (%)	Step (%)	
SpO <sub>2</sub> high limit	(low limit+1)~100	1	
SpO <sub>2</sub> low limit	0~(high limit-1)		
PR			
Measurement and display	25~250 bpm		
Resolution	1 bpm		
Accuracy	$\pm$ 2 bpm or $\pm$ 2%, whichever is greater		

Updating cycle	1 s	
Alarm limit	Range (bpm)	Step (bpm)
PR high limit	(low limit+1)~250	1
PR low limit	25~(high limit-1)	

#### A.13 TEMP

Measurement method	Thermistor method	
Channel	Dual-channel	
Probe type	YSI-2.252 K	
Measurement site	Body surface probe: armpit Body cavity probe: oral, rectum	
Measurement range	0~50 °C	
Resolution	0.1 °C	
Accuracy	±0.1 °C	
Updating cycle	About 1 s	
Minimum time for accurate measurement	Body surface: <100 s Body cavity: <80s	
Minimum time between measurement	Body surface probe: <100 s Body cavity probe: <80s	
Response mean time	<10 s	
Alarm response time	≤2 min	
Unit	°C or °F	
Alarm limit	Range (°C)	Step (°C)
T1/T2 high limit	(low limit +1)~50	1

T1/T2 low limit	0~(high limit-1)	
TD high limit	0~50	

#### A.14 IBP

Measurement method	Invasive and direct measurement	
Channel	Dual-channel	
Measurement range	-10~300 mmHg	
Resolution	1 mmHg	
Accuracy	$\pm 2\%$ or 1 mmHg, whichever is greater.	
Update time	About 1 s	
Pressure sensor		
Sensitivity	5 $\mu$ V/V/mmHg	
Impedance range	300~3000 $\Omega$	
Unit	mmHg, kPa, cmH2O	
Alarm limit	Range(mmHg)	Step(mmHg)
SYS ALM HI	((low limit+1)~350)	1
MEAN ALM HI		
DIA ALM HI		
SYS ALM LO	-50~(high limit-1)	1
MEAN ALM LO		
DIA ALM LO		

#### A.15 CO<sub>2</sub>

Measurement mode	Infrared radiation absorption technology
Sample Rate	50ml/min $\pm$ 10ml/min
Measurement parameters	EtCO <sub>2</sub> , InsCO <sub>2</sub> , AwRR

Measurement range	$\text{CO}_2$	0~150 mmHg
	$\text{InsCO}_2$	0~150 mmHg
	AwRR	2~150 rpm
Resolution	$\text{CO}_2$	0.1 mmHg(0~69 mmHg) 0.25 mmHg(70~150 mmHg)
	$\text{InsCO}_2$	0.1 mmHg(0~69 mmHg) 0.25 mmHg(70~150 mmHg)
Measurement accuracy	$\text{CO}_2$	$\pm 2 \text{ mmHg}$ , 0~40 mmHg Reading $\pm 5\%$ , 41~70 mmHg Reading $\pm 8\%$ , 71~100 mmHg Reading $\pm 10\%$ , 101~150 mmHg
	AwRR	$\pm 1 \text{ rpm}$
Initialization time	Mainstream	At 25 °C, inspiration/expiration $\text{CO}_2$ curve can be displayed within 15s, which meets all specification within 2 minutes.
	Sidestream	At 25 °C, inspiration/expiration $\text{CO}_2$ curve can be displayed within 20s, which meets all specification within 2 minutes.
Rise time for Main-stream	<60 ms—repeatable or disposable airway interface for adult	
	<60 ms—repeatable or disposable airway interface for pediatric	
Accuracy drift	meet accuracy requirements within 6 h	
Update time	1 s	
Delay time for sidestream	2~3 s	

AwRR apnea alarm delay	10~40 s	
Alarm limit	Range	Step 1
CO <sub>2</sub> ALM HI	(low limit +1) ~150 mmHg	
CO <sub>2</sub> ALM LO	0~(high limit -1)mmHg	
INS ALM HI	0~100 mmHg	
AWRR ALM HI	(low limit +1) ~150 rpm	
AWRR ALM LO	0~(high limit -1) rpm	

**Appendix B EMC Test Level Declaration –  
Guidance and Manufacture's Declaration**

**Table 1: Electromagnetic emission**

Guidance and manufacturer's declaration – electromagnetic emission		
The device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emission IEC 61000-3-3	Complies	The patient monitor is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Table 2: Electromagnetic immunity 1

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that they are used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines; ±1 kV for input/ output signal	±0.5 kV for power supply lines; ±1 kV for input/ output signal	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line ±2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% $U_T$ (>95% dip in $U_T$ ) for 0.5 cycle; 40% $U_T$ (60% dip in $U_T$ ) for 5 cycles; 70% $U_T$ (30% dip in $U_T$ ) for 25 cycles; <5% $U_T$ (>95% dip in $U_T$ ) for 5 sec	<5% $U_T$ (>95% dip in $U_T$ ) for 0.5 cycle; 40% $U_T$ (60% dip in $U_T$ ) for 5 cycles; 70% $U_T$ (30% dip in $U_T$ ) for 25 cycle; <5% $U_T$ (>95% dip in $U_T$ ) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruption, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power Frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE $U_T$ is the a.c. mains voltage prior to application of the test level.			

**Table 3: Electromagnetic immunity 3**

Guidance and manufacture's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that they are used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of <i>Patient Monitor</i> , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. <b>Recommended separation</b>

Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	<b>distance</b>  $d = 3.5 \sqrt{P}$ 150 kHz to 80 MHz $d = 3.5 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup> Interference may occur in the vicinity of equipment marked with the following symbol: 
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NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, object, and people.

<sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Patient Monitor is used exceeds the applicable RF compliance level above, Patient Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating Patient Monitor.

<sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m (80 – 800 MHz) and 3 V/m (800 – 2500 MHz).

**Table 4: Recommended separation distances**

<b>Recommended separation distances between portable and mobile RF communications equipment and the Patient Monitor</b>
The Patient Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Patient Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Patient Monitor as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 3.5 \sqrt{P}$	80 MHz to 800 MHz $d = 3.5 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.3500	0.3500	0.2334
0.1	1.1068	1.1068	0.7378
1	3.5000	3.5000	2.3334
10	11.0860	11.0860	7.3786
100	35.0000	35.0000	23.3334

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

**NOTE 1** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

**NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

## Appendix C System Alarm Prompt

PROMPT	CAUSE	Alarm Level	MEASURE
"XX HIGH"	XX value exceeds the higher alarm limit.	User-selectable	Check if the alarm limits are appropriate and the current situation of the patient.
"XX LOW"	XX value is below the lower alarm limit.	User-selectable	
XX represents the value of parameter such as HR, ST1, ST2, RR, SpO <sub>2</sub> , NIBP, etc. in the system.			
"ECG saturation, the signal is invalid"	ECG signal exceeds the measurement range.	LOW	Check the connection between the electrode and lead cable; Check the patient' condition.
"ECG WEAK SIGNAL"	The ECG signal of the patient is too small so that the system can not perform ECG analysis.	HIGH	Check the connection between the electrode and lead cable; Check the patient' condition.
"RESP APNEA"	The respiration signal of the patient is too small so that the system cannot perform RESP	HIGH	Check the connection of the linking wire and the current situation of the patient.

	analysis.		
"ASYSTOLE"	Patient suffers from Arr. Of ASYSTOLE.	HIGH	Check the patient' condition; Check the connection between the electrode and lead cable.
"VFIB/VTAC"	Patient suffers from Arr. of VFIB/VTAC.	HIGH	Check the patient' condition; Check the connection between the electrode and lead cable.
"COUPLET"	Patient suffers from Arr. of COUPLET.	User-selectable	Check the patient' condition; Check the connection between the electrode and lead cable.
"BIGEMINY"	Patient suffers from Arr. Of BIGEMINY.	User-selectable	Check the patient' condition; Check the connection between the electrode and lead cable.
"TRIGEMINY"	Patient suffers from Arr. of TRIGEMINY.	User-selectable	Check the patient' condition; Check the connection between the electrode and lead cable.
"R ON T"	Patient suffers from Arr. of R ON T.	User-selectable	Check the patient' condition; Check the connection between the electrode and lead cable.
"TACHY"	Patient suffers from	User-selectable	Check the patient'

	TACHY.		condition; Check the connection between the electrode and lead cable.
"BRADY"	Patient suffers from BRADY.	User-selectable	Check the patient' condition; Check the connection between the electrode and lead cable.
"VT>2"	Patient suffers from Arr. of VT>2.	User-selectable	Check the patient' condition; Check the connection between the electrode and lead cable.
"MISSED BEATS"	Patient suffers from Arr. of MISSED BEATS.	User-selectable	Check the patient' condition; Check the connection between the electrode and lead cable.
"PNP"	The pacemaker is not paced.	User-selectable	Check the connection of the pacemaker; check the connection between the electrode and lead cable; check the patient' condition.
"PNC"	No pacemaker signal is captured.	User-selectable	Check the patient' condition; Check the connection between the electrode and lead cable.

"ECG LEAD OFF or RESP LEAD OFF"	RL lead of ECG is not connected correctly or ECG lead is not connected correctly.	LOW	Check the connection of RL lead or ECG lead cable.
"V LEAD OFF"	The V lead of ECG is not connected correctly.	LOW	Check the connection of V lead.
"LL LEAD OFF"	The LL lead of ECG is not connected correctly.	LOW	Check the connection of LL lead.
"LA LEAD OFF"	The LA lead of ECG is not connected correctly.	LOW	Check the connection of LA lead.
"RA LEAD OFF"	The RA lead of ECG is not connected correctly.	LOW	Check the connection of RA lead.
"RESP LEAD OFF"	At least one lead among RA, RL and LL is not connected correctly.	LOW	Check the connection of RA, RL or LL lead.
"SpO <sub>2</sub> SENSOR OFF"	SpO <sub>2</sub> sensor is not connected correctly.	LOW	Check the connection of SpO <sub>2</sub> sensor.
"SpO <sub>2</sub> SEARCH	The pulse signal of the patient is too	HIGH	Check the connection of sensor; Check the

"TIMEOUT"	small so that the system cannot perform pulse signal analysis.		patient' condition.
"T1 SENSOR OFF"	T1 sensor is not connected correctly.	LOW	Check the connection of T1 sensor.
"T2 SENSOR OFF"	T2 sensor is not connected correctly.	LOW	Check the connection of T2 sensor.
"ECG NOISE"	larger interference signals appear in the ECG signals.	LOW	Check the connection of ECG lead cable; Check the current situation of the patient. Check if the patient moves a lot.
"XX COMM ERR"	XX module can't communicate normally with the host.	HIGH	Re-start up the monitor, if the error still exists, contact the manufacturer.
XX represents all the parameter modules in the system such as ECG, NIBP, SpO <sub>2</sub> , etc.			
"KEYBOARD COMM ERR"	The keyboard has failures, which cannot be used.	HIGH	Contact the manufacturer for repair.
"WIRELESS"	The network part in	MED	Contact the

CONNECT ERROR"	the system appear problems, so the system can't achieve network function.		manufacturer for repair.
"CAN'T FIND WIRELESS DEVICE"			
"LOW POWER"	Low battery.	HIGH	Charge the battery by connecting the AC cord.
"RECODER OUT OF PAPER"	No recording paper	LOW	Install the recording paper.
"RECODER ERROR"	The recorder communicates abnormally.	LOW	Turn off the device and restart it.
"NIBP INIT ERR"	NIBP initialization error	LOW	Execute the reset program in the NIBP menu. If the failure still exists, contact the manufacturer for repair.
"NIBP SELFTEST ERR"			
"NIBP ILLEGALLY RESET"	During NIBP measurement, illegal reset occurs.	LOW	Check the airway of NIBP to check if there are clogs. Then measure again, if the failure still exists, contact the

			manufacturer for repair.
"NIBP COMM ERR"	The NIBP communication part has problem.	HIGH	Execute the reset program in the NIBP menu. If the failure still exists, contact the manufacturer for repair.
"NIBP LOOSE CUFF"	The NIBP cuff is not connected correctly.	LOW	Re-connect the NIBP cuff.
"NIBP AIR LEAK"	The NIBP cuff is not connected correctly or there are leaks in the airway.	LOW	Check the connection of each part or replace with a new cuff. If the failure still exists, contact the manufacturer for repair.
"NIBP AIR PRESSURE ERROR"	Problem happens when measuring the curve. The system can't perform measurement, analysis or calculation.	LOW	Check the connection of each part or replace with a new cuff. If the failure still exists, contact the manufacturer for repair.
"NIBP WEAK SIGNAL"	Problem happens when measuring the curve. The system can't perform measurement, analysis or	LOW	Check if the setup of patient type is correct. Check the connection of each part or replace with a new cuff. If the failure still exists, contact the manufacturer for repair.

	calculation.		manufacturer for repair
"NIBP RANGE EXCEEDED"	Problem happens when measuring the curve. The system cannot perform measurement, analysis or calculation.	LOW	Check the connection of each part or replace with a new cuff. If the failure still exists, contact the manufacturer for repair.
"NIBP EXCESSIVE MOTION"	The patient's arm moves.	LOW	Check the connection of each part and the patient situation. Measure again, if the failure still exists, contact the manufacturer for repair.
"NIBP OVER PRESSURE"	Perhaps folds exist in the airway.	LOW	Check for the smoothness in the airway and patient situation. Measure again, if the failure still exists, contact the manufacturer for repair.
"NIBP SIGNAL SATURATED"	Problem happens when measuring the curve. The system cannot perform measurement,	LOW	Check the connection of each part and the patient situation. Measure again, if the failure still exists, contact the manufacturer

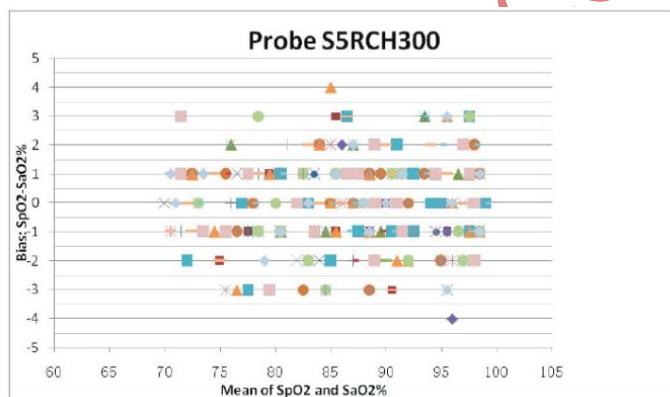
	analysis or calculation.		for repair.
"NIBP TIME OUT"	Problem happens when measuring the curve. The system cannot perform measurement, analysis or calculation.	LOW	Check the connection of each part and the patient situation. Measure again, if the failure still exists, contact the manufacturer for repair.
"NIBP CUFF TYPE ERR"	Perhaps the used cuff does not fit the patient type sey.	LOW	Check if the patient type is set up correctly. Check whether the cuff conforms to the patient's type.
"NIBP PNEUMATIC LEAK"	NIBP airway has leaks.	LOW	Check the connection of each part or replace with a new cuff. If the failure still exists, contact the manufacturer for repair.
"NIBP SYSTEM FAILURE"	Problem happens when measuring the curve. The system cannot perform measurement, analysis or calculation.	LOW	Check the connection of each part and the patient situation. Measure again, if the failure still exists, contact the manufacturer for repair.

## Appendix D SpO<sub>2</sub> Clinical Information

Clinical Result information for each sensor

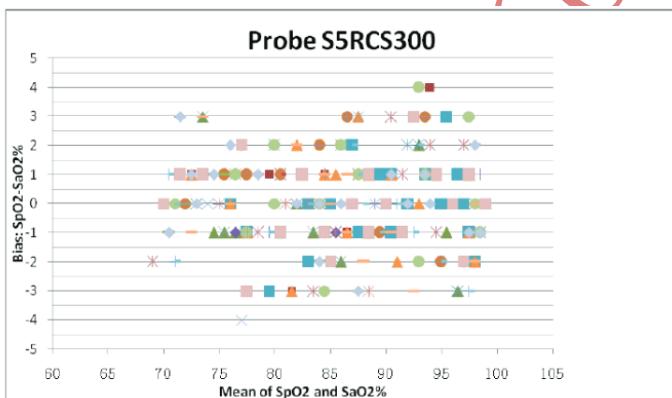
The table below shows ARMS values measured using SpO<sub>2</sub> sensor (S5RCH300) with Patient Monitor in a clinical study.

Hemoximeter SaO <sub>2</sub> Range	70-80	80-90	90-95	95-100	Total
Effective Data Count	85	149	82	84	400
Exclusion Count	89	156	91	97	433
Mean	0.01	0.19	0.17	-0.07	0.10
Standard Deviation	1.27	1.35	1.55	1.40	1.39
Upper/lower 95% limit	2.50/-4.27	2.85/-2.50	3.22/-2.88	2.68/-2.82	2.82/-2.63
Root Mean Square (RMS)	1.26	1.36	1.55	1.40	1.39



The table below shows ARMS values measured using SpO<sub>2</sub> sensor (S5RCS300) with Patient Monitor in a clinical study.

Hemoximeter SaO <sub>2</sub> Range	70-80	80-90	90-95	95-100	Total
Effective Data Count	83	151	84	82	400
Exclusion Count	92	159	86	87	424
Mean	0.29	0.07	0.57	-0.28	0.15
Standard Deviation	1.38	1.39	1.37	1.34	1.40
Upper/lower 95% limit	3.00/-2.42	2.80/-2.67	3.26/-2.12	2.34/-2.90	2.89/-2.60
Root Mean Square (RMS)	1.41	1.39	1.48	1.36	1.41



## Appendix E Abbreviations

### E.1 Unit list

Abbreviation	Description
$\mu\text{A}$	microampere
$\mu\text{V}$	microvolt
A	ampere
Ah	ampere hour
bpm	beat per minute
$^{\circ}\text{C}$	centigrade
cm	centimeter
dB	decibel
$^{\circ}\text{F}$	fahrenheit
g	gram
h	hour
Hz	hertz
inch	inch
k	kilo
kg	kilogram
kPa	kilopascal
L	litre
lb	pound
m	meter
mAh	milliampere hour
mcg	microgram
mEq	milli-equivalents

mg	milligram
min	minute
ml	milliliter
mm	millimeter
mmHg	millimeters of mercury
cmH <sub>2</sub> O	centimeters of water
ms	millisecond
mV	millivolt
mW	milliwatt
MΩ	megaohm
nm	nanometer
rpm	breaths per minute
s	second
V	volt
VA	volt ampere
Ω	ohm
W	watt

#### E.2 Terminology list

Abbreviation	Description
AC	alternating current
Adu	adult
AHA	American Heart Association
Art	arterial
aVF	left foot augmented lead
aVL	left arm augmented lead
aVR	right arm augmented lead

AwRR	airway respiratory rate
BP	blood pressure
CO	cardiac output
CCU	cardiac (coronary) care unit
CI	cardiac index
CISPR	International Special Committee on Radio Interference
CMS	central monitoring system
CO <sub>2</sub>	carbon dioxide
COHb	carboxyhemoglobin
CVP	central venous pressure
DC	direct current
Dia	diastolic
DPI	dot per inch
ECG	electrocardiograph
EMC	electromagnetic compatibility
EMI	electromagnetic interference
ESD	electro-static discharge
ESU	electrosurgical unit
Et	end-tidal
EtCO <sub>2</sub>	end-tidal carbon dioxide
EtO	ethylene oxide
HR	heart rate
ICG	Impedance cardiography
ICT/B	intracranial catheter tip pressure transducer
ICU	intensive care unit
IEC	International Electrotechnical Commission

IEEE	Institute of Electrical and Electronic Engineers
IBP	Invasive brood pressure
IP	internet protocol
LA	left arm
LAP	left atrial pressure
LCD	liquid crystal display
LED	light emitting diode
LL	left leg(electrode)
MAP	mean arterial pressure
MethHb	methemoglobin
MRI	magnetic resonance imaging
N/A	not applied
Neo	neonate
NIBP	noninvasive blood pressure
oxyCRG	oxygen cardio-respirogram
Ped	pediatric
Pleth	plethysmogram
PR	pulse rate
PVC	premature ventricular contraction
RA	right arm
Rec	record, recording
Resp	respiration
RL	right leg(electrode)
RR	respiration rate
SpO <sub>2</sub>	arterial oxygen saturation from pulse oximetry
SV	stroke volume

SYS	systolic pressure
TBW	Total body water
TD	temperature difference
TPR	total peripheral resistance
Temp	temperature
USB	universal serial bus

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